2004

Report of the Auditor General of Canada to the House of Commons

MARCH

A Message From the Auditor General of Canada

Main Points

Office of the Auditor General of Canada

The March 2004 Report of the Auditor General of Canada comprises seven chapters, and a Message from the Auditor General and Main Points. The main table of contents is found at the end of this publication.

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© Minister of Public Works and Government Services Canada 2004
Cat. No. FA1-2004/1-0E
ISBN 0-662-36240-3

Auditor General of Canada
Vérificatrice générale du Canada

To the Honourable Speaker of the House of Commons:

I have the honour to transmit herewith my first Report of 2004 to the House of Commons, which is to be tabled in the House in accordance with the provisions of subsection 7(5) of the *Auditor General Act*.

This Report includes an addendum containing verbatim copies of environmental petitions and ministers' responses, received under the *Auditor General Act* from 19 July 2003 to 21 January 2004.

Sheila Fraser

Sheila Fraser, FCA
Auditor General of Canada

OTTAWA, 30 March 2004

104-04186/

A Message From the Auditor General of Canada

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National Security in Canada—The 2001 Anti-Terrorism Initiative

One of the most important areas in which Canadians rely on the federal government to safeguard our well-being is national security. As individuals, we cannot monitor or influence national security on our own—we must look to the government to manage the risks that threaten our security and that of our families.

This report includes my Office's first broad look at national security since the unprecedented terrorist attacks on the United States on September 11, 2001. As Canadians will no doubt recall, the immediate impact on Canada included the shutdown of civil air transport and the grounding of hundreds of international air passengers in locations as far afield as Gander, Newfoundland and Whitehorse, Yukon. These events left many Canadians suddenly feeling vulnerable and insecure.

Soon after the attacks, the government responded with a number of related projects designed to improve Canadian security. It established the Ad Hoc Cabinet Committee on Public Security and Anti-Terrorism and, in the 2001 Budget, allocated $7.7 billion in new funding to enhance security, emergency preparedness, and infrastructure at our borders. This new funding began in 2001–02 and was to continue for another five years.

Our audit focussed on the overall management of the initiative to enhance national security and the co-ordination of intelligence among departments and agencies—in particular, their ability to provide adequate information to enforcement personnel. It also examined several specific issues: the interoperability of security and intelligence information systems and the sharing of information; fingerprint identification systems; the use of watch lists for border control; and the security clearance of airport workers requiring access to restricted areas.

In December 2003, domestic security agencies were consolidated into a new department, Public Safety and Emergency Preparedness Canada. Our audit assessed the management of national security prior to this reorganization. We found that most proposals submitted by departments for funding under the initiative were directly linked to objectives announced in the Budget. However, we found no evidence that the Privy Council Office, the Department of Finance Canada, and the Treasury Board Secretariat had based their review and approval of departmental projects on a national threat and risk assessment—a tool that could have helped ensure that a project was not given a higher or a lower priority than was warranted. In some cases, projects funded appeared to be related to existing programs of public safety and defence and not a direct response to the threat of terrorism. At the same time, some projects clearly related to combatting terrorism were not fully funded.

Our audit also found deficiencies in the way intelligence is managed across government. A lack of co-ordination has led to some gaps and potential duplications in intelligence coverage. The government as a whole failed to adequately assess intelligence lessons learned from critical incidents such as September 11 and to develop and systematically follow up on needed improvements.

One of the main security challenges the government faces at ports of entry is allowing the free flow of goods and legitimate travellers while keeping terrorists out. Canadians want to know if the interconnected systems that contribute to border security are effective; those who travel want to know if the inconveniences caused by security measures do indeed contribute to greater security.

Up-to-date watch lists can help intercept terrorists and other criminals at our borders. However, we found that watch lists used by departments and agencies to screen visa applicants, refugee claimants, and travellers seeking to enter Canada have significant gaps and errors. Responsibility for watch lists is shared by several departments and agencies. We found an overall lack of quality control of this vital tool: no one is monitoring the accuracy and timeliness of the data across the several agencies involved. Furthermore, the 25,000 Canadian passports lost or stolen each year do not appear on border control watch lists, despite their potential for use by terrorists or other criminals. Missing names reduce the usefulness of watch lists as a security tool, and out-of-date information can inconvenience legitimate travellers unnecessarily.

We also concluded that applicants for clearance to restricted airport areas are not being checked against available intelligence databases. As a result, many individuals whose reliability is questionable have access to restricted areas. We asked the RCMP to review the files of a sample group that had been issued clearances by Transport Canada; 5.5 percent of those with access to restricted areas at five Canadian airports were found to have possible criminal associations that warrant further investigation and possibly withdrawal of their security clearances. If these results were generalized to the total number of people holding clearances at the five airports, the number warranting further investigation would amount to some 4,500 individuals. Spending on passenger and cargo security will be of limited value unless air transportation workers with access to aircraft are trustworthy.

On 12 December 2003, after we had completed most of our examination, the Prime Minister announced significant changes to departments and agencies involved in national security. These include the creation of Public Safety and Emergency Preparedness Canada, the Canada Border Services Agency, and the new position of National Security Advisor to the Prime Minister.

Overall, should Canadians be indignant about the government's management of national security in light of the specific deficiencies we found? Or should they be reassured that the federal government acted quickly and is on the right track in its efforts to solve problems that became obvious only following September 11, 2001?

Clearly, the deficiencies we've noted are serious and need to be addressed on an urgent basis. At the same time, many things changed on September 11, 2001—our perception of risk, our feeling of vulnerability, our definition of national security and the amount of inconvenience we are prepared to tolerate in order to attain it—and Canada, like other governments around the world, must now adjust to new realities. It is worth noting that Canada's performance in managing national security in the past two and a half years is consistent with that of our international peers. Other countries, including the United States, have examined similar areas and have reported findings comparable with those of our audit.

National security is one of several areas of federal government responsibility considered in this Report that contribute directly to the well-being of Canadians. Other chapters focus on the regulation of medical devices, the regulation of plant biotechnology products, and the conduct of leading-edge scientific research.

Health Canada—Regulation of Medical Devices

Modern health care relies more and more on using medical devices—blood test kits, diagnostic imaging equipment, and heart valves, for example—to diagnose, treat, mitigate, and prevent diseases and medical conditions.

Along with the benefits they provide, medical devices carry some level of potential risk: their quality and safety can never be guaranteed absolutely. The public has limited control over those risks and must trust health care professionals and the manufacturers of medical devices to provide safe and effective products and services.

Under the *Food and Drug Act*, Health Canada is responsible for protecting the public from undue risks to health and safety. Thus, it must weigh the benefits of using medical devices against the associated risks to determine whether or not particular devices should be available to Canadians.

Our audit found that Health Canada has made good progress in managing risks before medical devices are made available for sale but needs to better manage risks after the products are on the market. It needs to adopt a more proactive inspection program to verify that industry is complying with regulations, and it needs to better manage the risks related to the sale of unlicensed medical devices.

An improved surveillance system is also required to provide timely, accurate, and complete information about adverse events after devices are in use. And once safety concerns are identified, there must be better communication with those who need this information.

Ultimately, we are concerned that Health Canada still does not have a comprehensive program in place to protect the health and safety of Canadians from the risks related to medical devices, even though it committed to such a program over a decade ago. The failure to deliver such a program could translate into growing risks—of both injury to Canadians and liability to the Department.

Canadian Food Inspection Agency—Regulation of Plants with Novel Traits

In the past few years, Canada's biotechnology sector has seen rapid growth in the number of companies and in the number of their products and processes on the market. The federal government has identified biotechnology as key to the country's economic growth and international competitiveness and has invested heavily in its research, promotion, and regulation.

Biotechnology has been broadly defined as the use of biological processes, especially genetic manipulation, for industrial and other purposes. It can refer to traditional as well as modern processes. Modern biotechnology enables scientists to transfer specific genetic traits directly from one organism to another, including species that would not naturally interbreed. Concerns have been expressed about the potential social, ethical, and economic risks of modern biotechnology. There are also concerns about the potential impacts on the environment and the potential health effects of new products developed through biotechnology.

A strong regulatory framework is essential if Canada is to capitalize on the potential benefits of modern biotechnology while appropriately managing the potential risks. Our audit examined how the Canadian Food Inspection Agency regulates the environmental release of plants developed through modern biotechnology, which are included in a broad category called plants with novel traits. Approval of a plant with a novel trait that harms the environment or human health could undermine public confidence in the regulatory system.

Our audit identified weaknesses in how the Agency identifies and manages risks posed by the environmental release of plants with novel traits. For example, there is a risk that undeclared and undetected plants with novel traits are being imported into Canada and may therefore be escaping Canada's regulatory system. Our findings also suggest there is a risk that unapproved ornamental plants with novel traits could be present in Canada. Moreover, the Agency did not have complete documentary evidence to show how it evaluates the long-term harmful effects on the environment, as it is legally required to do, before authorizing the unconfined release of plants with novel traits.

Our findings provide an early warning signal that the Agency's regulatory processes for plants with novel traits need strengthening. This is especially important given that the Agency expects the next generation of plants with novel traits to pose new and more complex environmental risks.

National Research Council Canada—Management of Leading-Edge Research

The National Research Council (NRC) has earned international recognition in a broad diversity of scientific disciplines. It has a long history of scientific discoveries that contribute to the well-being of Canadians and others worldwide.

While most of the NRC's research is well-managed, our audit found that the leading-edge research funded predominantly by parliamentary appropriations is not subjected to a rigorous priority-setting framework at all the institutes under its umbrella. The NRC needs to review its corporate mechanisms for setting priorities to avoid an imbalance between its research activities and the funding it has available. Although it has had no increase in its core budget, it is currently launching several long-term initiatives that call for major increases in infrastructure and staff. At the same time, funding most of its existing activities is proving to be a challenge.

Strengthening governance and accountability would improve the NRC's ability to set priorities and manage its resources accordingly. Our audit found that the Governing Council is not fulfilling its duty to control and direct the work of the organization through the President as required under the *National Research Council Act*. The Governing Council's responsibilities are not defined clearly or well understood by Council members.

To be a leading research and development organization, the NRC must be able to continue recruiting and retaining highly qualified researchers. Yet a shortage of researchers is anticipated. The NRC has not yet assessed the risks or the opportunities in its human resources management in order to address future key challenges in research institutes. Further, the NRC needs a coherent and comprehensive action plan to implement its strategic direction.

After seven years of collecting and reporting data on its corporate performance, the NRC is continuing to improve its performance measurement and reporting through a new corporate framework. It now needs to strengthen and implement that framework and to address weaknesses in its performance report.

Managing Government: Using Financial Information

Programs and services that improve the well-being of Canadians need to be managed prudently if Canadians are to receive value for the money spent. Complete financial information and strong internal controls are vital components of the effective management and good stewardship of public funds.

After facing many challenges, and with considerable effort, the government prepared its 2003 summary financial statements on a full accrual basis of accounting. This achievement has made Canada a world leader among national governments in financial reporting.

This new basis for preparing financial information provides a more complete picture of the full financial scope of government activities and enables legislators to hold the government more accountable for the stewardship of its assets, the full costs of its programs, and its ability to meet short-term and long-term financial obligations. Accrual financial information can also help improve decision making in departments and agencies by showing managers the full costs of providing programs and services.

The adoption of accrual accounting at the summary level was never intended as an end in itself but as part of a wider initiative to improve financial management and control in the federal government. We urge the government to take the next steps and incorporate financial information on an accrual basis in its daily decision making and its management and reporting practices. Departments must also strengthen their internal control systems. Integrated and comprehensive internal control systems play a significant role in ensuring that high-quality financial information is available.

In our view, it is time for the government to finally implement accrual appropriations and budgeting at the departmental level. Until government-wide and departmental budgeting, financial reporting, and appropriations are put on a common basis, effective use of financial management information in the government will not be achieved.

Canada Revenue Agency—Audits of Small and Medium Enterprises

As the trend to self-employment increases, small and medium-sized enterprises represent a growing segment of the economy—one that is most at risk of participation in the underground economy. The Canada Revenue Agency conducts audits of businesses in this sector to improve compliance with tax legislation, thus helping to protect the tax base for the benefit of all Canadians.

To carry out this important role adequately, the Agency needs to make several improvements. It needs an overall analysis of all threats to the tax base to determine whether its current resourcing decisions are the most appropriate for each of its compliance activities, including its audits of small and medium enterprises. An audit strategy that better reflects risk would allow the Agency to allocate its resources to the areas of highest risk and to intervene, where necessary, while reducing the burden on compliant taxpayers. Currently in the tax services offices, staffing for audits of small and medium enterprises is based on the gross revenue reported by the taxpayers served rather than on the level of risk and complexity of their tax files. The Agency's own studies indicate that many of the small and medium enterprises it has audited represented little or no risk.

The Agency does not have the information it needs to measure compliance over time and thereby assess the effectiveness of its activities. It has not yet tested the results of initiatives undertaken to strengthen compliance by small and medium enterprises with the goods and services tax and harmonized sales tax.

Although it has not yet completed a review to determine if the penalties provided for in tax legislation are improving compliance and increasing public confidence, the Agency has reduced the penalties on employers who are late in remitting income taxes withheld from employee salaries. We also noted that the Agency did not have the legislative authority to reduce these penalties.

Managing Government: A Study of the Role of the Treasury Board and its Secretariat

The government has launched an ambitious agenda for strengthening management across the federal public sector—one that stresses managing in a manner that preserves public trust; enhances economy, efficiency, and effectiveness; and ensures accountability. The Treasury Board of Canada and its Secretariat play an important role in developing and overseeing the implementation of this agenda across departments.

To provide Parliament with information on the key challenges the government faces in translating this agenda into tangible improvements in management, we carried out the study included in this Report. It is the first step toward a longer-term audit plan for our Office, which will report in the coming years on how well the federal government's management agenda is being implemented.

Main Points

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National Research Council Canada
Management of Leading-Edge Research

Chapter 1

Main Points

1.1 The National Research Council's (NRC) Governing Council is not fulfilling its duties to direct and control the work of the corporation through the President as required under the *National Research Council Act*. The Governing Council's responsibilities are not clearly defined and therefore are not well understood by the Council members. Thus, the Governing Council lacks important governance and accountability structures. As a result, there is no effective challenge to management plans and decisions. The *National Research Council Act* has not been updated to incorporate best practices for corporate governance, such as those in more recent legislation establishing a governing council.

1.2 The NRC needs to review its corporate mechanisms for setting priorities to avoid an imbalance between its research activities and available funding. Although it has had no core budget increase, it is currently launching several long-term initiatives that include major increases in infrastructure and staff. Meanwhile, the NRC is facing important challenges in funding most of its current activities.

Background and other observations

1.3 The NRC has earned international recognition in a broad diversity of scientific disciplines. It has a long history of making valuable scientific discoveries that contribute to the well-being of Canadians and others worldwide. While most of the research at the NRC is well managed, the leading-edge research funded predominantly by parliamentary appropriations is not subjected to a rigorous priority-setting framework at all institutes. If this situation continues, core competencies needed by the NRC to maintain Canada's competitive edge in scientific research worldwide could be eroded. In our view, the weakness in the priority-setting framework results from a failure to implement strategic plans and guidelines.

1.4 With an anticipated shortage of researchers looming, the NRC needs to be able to continue recruiting and retaining highly qualified researchers to be a leading research and development organization. To do so, the NRC must further develop its human resources management strategic direction, based on an assessment of the risks and opportunities to address key challenges in institutes. Further, it needs to have a coherent and comprehensive action plan to implement its strategic direction.

1.5 After seven years of collecting and reporting corporate performance data, the NRC is continuing to improve its performance measurement and reporting practices through a new corporate performance management framework. It now needs to strengthen and implement that framework and to address weaknesses in its Performance Report.

The National Research Council has responded. The National Research Council has accepted and agreed with all our recommendations and has provided individual responses. The responses include statements of actions already underway or planned to address the recommendations.

Health Canada
Regulation of Medical Devices

Chapter 2

Main Points

2.1 While Health Canada has made progress in important aspects of managing risks related to medical devices before they are made available for sale, it needs to better manage risk after they are available for sale. As a result of the gaps in its Medical Devices Program, Health Canada does not have a comprehensive program to protect the health and safety of Canadians from risks related to medical devices, even though it committed to such a program over a decade ago. Its failure to deliver such a program compromises Health Canada's ability to protect health and safety, which could translate into a growing risk—risk of both injury and liability.

2.2 The current Medical Devices Program manages risks before products are made available for sale, through quality systems requirements and pre-market activities.

2.3 However, to better manage risks after products are available for sale, Health Canada needs to have a more proactive inspection program at the post-market phase to verify that industry is complying with the Medical Devices Regulations, and it needs a better approach to managing risks related to the sale of unlicensed medical devices. An improved post-market surveillance system is also required to provide timely, accurate, and complete information about adverse events once devices are in use. And once safety concerns are identified, there must be better communication in a timely manner with those who need to know.

2.4 Health Canada is taking only limited action to address the risks posed by the reuse of single-use devices. As one of the entities responsible for protecting the health and safety of Canadians, it must take action immediately.

Background and other observations

2.5 Equal and timely access to quality health care is a priority for Canadians. This includes timely access to medical devices, which play an important role in all stages of the delivery of quality health care. Medical devices such as blood test kits, diagnostic imaging equipment, and heart valves are used to diagnose, treat, mitigate, and prevent diseases and medical conditions.

2.6 The Medical Device Review Committee was established in 1991 to formulate recommendations to the Minister of Health concerning the regulation of medical devices and associated activities. A 1992 report of the Committee was used to prepare the Development Plan for an Improved

Medical Devices Regulatory Program. This Plan and the consultation with stakeholders that followed formed the basis of a new Medical Devices Program that began with the introduction of new Medical Devices Regulations in 1998. Since then, Health Canada has introduced some new activities and made improvements to some existing activities, but significant gaps and weaknesses remain.

2.7 Our audit examined how Health Canada manages the risks and benefits related to medical devices at each stage of the product life cycle of a licensed device. Because Health Canada responded to the Medical Devices Review Committee's report and made efforts to implement changes, we used the Department's response as the standard against which we measured the Medical Devices Program. We also examined how the achievements and challenges facing this Program were measured and reported to Parliament.

2.8 Health Canada is aware of the gaps and weaknesses in the Program, but has made limited efforts to address them. Limited financial and human resources and limited progress in advancing international regulatory co-operation prevent Health Canada from addressing these gaps and weaknesses. This in turn, prevents it from delivering the Medical Devices Program as designed.

2.9 Our findings indicate that the current Program is not sustainable. As such, Health Canada must make a choice: It must provide adequate resources to deliver the Program as designed or redesign the Program and the Regulations to allow for health and safety risks to be managed in a way that requires fewer resources.

2.10 Health Canada needs to act to ensure that Canadians have timely access to all available medical devices. It also needs to play a more active role in the conduct of investigational testing.

2.11 Finally, Health Canada needs to improve its evaluation, measurement, and reporting of the results of its Medical Devices Program. This is especially important given the challenges that the Program faces and the questions about continuing with the current Program or redesigning it.

The Department has responded. Health Canada's responses to our recommendations are included in this chapter. The Department has responded positively to our recommendations and has agreed to take corrective action. In some instances, the action is already under way.

National Security in Canada
The 2001 Anti-Terrorism Initiative

Chapter 3 Main Points

3.1 In response to the September 11 terrorist attacks on the United States in 2001, the Canadian government took several steps: It established the Ad Hoc Cabinet Committee on Public Security and Anti-Terrorism, chaired by the Deputy Prime Minister; mobilized the military, the RCMP, and the public service to manage the initial crisis; and then developed a long-range initiative to improve Canadian security. In the 2001 Budget, the government allocated $7.7 billion in new funds to be spent over the next five years on the Public Security and Anti-Terrorism initiative to enhance security for Canadians.

3.2 Our audit examined the overall management of the Public Security and Anti-Terrorism initiative. We also examined the co-ordination of intelligence among departments and agencies and their ability to provide adequate information to enforcement personnel. In addition, we examined selected issues in greater detail—the interoperability of security and intelligence information systems; fingerprint identification; and the assessment of airport workers who require clearances to restricted areas. Other countries, including the United States, have examined similar areas and reported findings comparable with those of our audit.

3.3 We found that the government had developed management systems to direct and control spending and reporting on activities under the initiative. The vast majority of funds allocated in the 2001 Budget have been channelled to priority areas. In addition, the Treasury Board Secretariat is tracking spending and attempting to assess the security improvements achieved by the initiative. However, we found that the government did not have a management framework that would guide investment, management, and development decisions and allow it to direct complementary actions in separate agencies or to make choices between conflicting priorities.

3.4 The government as a whole failed to achieve improvements in the ability of security information systems to communicate with each other. Consequently, needed improvements will be delayed by several years. Moreover, even as the government was launching programs that would create new needs for fingerprint identification, projects that would have helped it to deal with the increased demand were not included in the initiative.

3.5 We also found deficiencies in the way intelligence is managed across the government. A lack of co-ordination has led to gaps in intelligence coverage as well as duplication. The government as a whole did not adequately assess intelligence lessons learned from critical incidents such as September 11 or develop and follow up on improvement programs. Individual agencies have created new co-ordinating mechanisms, but some departments are still not participating in them.

3.6 We found gaps and inconsistencies in the watch lists used to screen visa applicants, refugee claimants, and travellers seeking to enter Canada. There is no overall quality control of this vital function, which is spread over several departments and agencies. No one monitors delays in the entry or the quality of the data on watch lists.

3.7 Finally, criminal intelligence data are not used to screen applicants for clearance to restricted areas at airports, meaning that security clearances are issued without checking applicants for criminal association. Transport Canada is not provided with all the information available to police and therefore has issued restricted area clearances to many individuals whose reliability must be questioned. Unless air transportation workers with access to aircraft are reliable, spending on passenger and cargo security will be of reduced value.

The departments and agencies have responded. In general, they have agreed with our recommendations although commitments toward remedial action are sometimes vague. We found that the responses from the Canada Border Services Agency and Public Safety and Emergency Preparedness Canada provide a clear picture of their intentions.

Canadian Food Inspection Agency
Regulation of Plants with Novel Traits

Chapter 4

Main Points

4.1 The Canadian Food Inspection Agency regulates the environmental release of plants developed through biotechnology, which are included in a broad category called plants with novel traits. Our audit identified weaknesses in the Agency's practices related to the management of risks associated with the environmental release of these plants. Our findings raise concerns that the Agency may not be regulating the unconfined release of these plants in a consistent manner.

4.2 Our audit focussed on the processes that the Canadian Food Inspection Agency had in place to ensure that it was meeting its responsibilities with respect to the regulation of plants with novel traits. As such, our audit procedures were not designed to determine whether undeclared and undetected plants with novel traits were entering Canada, whether any unauthorized ornamental plants with novel traits were present in Canada, or whether the Agency had approved any plants with novel traits that should not have been. No information came to our attention that any of these situations had occurred.

4.3 Our findings provide an early warning signal that some important aspects of the Agency's regulatory processes for plants with novel traits need strengthening. Given that the next generation of plants with novel traits could pose new and more complex environmental risks, it is important that the Agency act on our recommendations if it is to be prepared to meet these future challenges.

4.4 We found that there is a risk that undeclared and undetected plants with novel traits could be imported into Canada, and may therefore escape Canada's regulatory system. There is also a risk that unapproved ornamental plants with novel traits could be present in Canada.

4.5 The Agency has required insect resistance management as a condition whenever it authorizes insect-resistant plants with novel traits. However, the Agency's audits of conditions for unconfined release of insect-resistant corn have not yet enabled it to fully verify compliance with the conditions imposed.

4.6 To maintain quality and consistency in the delivery of the regulatory program for plants with novel traits, we would expect the Agency to have documented and implemented a quality management system to guide its evaluations. To support its decisions regarding unconfined release, we found deficiencies in standard operating procedures, a lack of complete documentation in the files, and incomplete definition of data quality standards to guide the evaluations. For example we found that the Agency did not have complete documentary evidence and, therefore, was not transparent about how it was evaluating the long-term effects on the environment before authorizing unconfined release of plants with novel traits.

Background and other observations

4.7 The Government of Canada has identified biotechnology as a key industry for economic growth and international competitiveness. Consequently it has invested heavily in research, promotion, economic development, and the regulation of biotechnology.

4.8 Three federal organizations currently share responsibility for regulating products developed through biotechnology for their potential effects on health and the environment. This audit focussed on the Agency's regulatory activities to manage the environmental risks of plants with novel traits, a broad category that includes plants developed through biotechnology. The Agency states that Canada is the only country to use this regulatory approach.

4.9 Having and implementing a strong regulatory framework is essential if Canada is to capitalize on the potential benefits of plants with novel traits while appropriately managing the potential risks. Approval of a plant with a novel trait that harms the environment or human health could undermine public confidence in the regulatory system.

The Agency has responded. The Agency agrees with our recommendations. Plans and actions it has underway are indicated in the responses in the chapter.

Canada Revenue Agency
Audits of Small and Medium Enterprises

Chapter 5

Main Points

5.1 The Canada Revenue Agency does not have the resources to be everywhere at once. It has to make trade-offs in deciding where to deploy resources to deal with competing threats to the tax base. To do this, it must ensure that all threats to the tax base are identified and considered in a consistent manner.

5.2 The Agency's aim is to improve compliance with tax legislation. However, it does not have the necessary information to enable it to measure compliance over time and, therefore, the effectiveness of its activities. For example, the Agency has not estimated the amount by which it overpays GST/HST refund claims. It is only now in the process of developing a compliance measurement framework.

5.3 The small and medium enterprise audit strategy could better reflect risk. Staffing in each tax services office for small and medium enterprise audits depends on the population of the different segments of taxpayers served by the office rather than the risk and complexity inherent in those taxpayers' affairs. To meet audit coverage targets, tax services offices can restrict up to 50 percent of their audits to one to three issues. These restricted audits take less time to complete but do not permit an overall evaluation of the taxpayer's compliance with tax laws. In addition, two studies conducted by the Agency found that 40 percent of all small and medium enterprises audited in a given year had little or no potential tax at risk according to the Agency's computerized risk evaluation system.

5.4 The Agency's own quality assurance reviews show that audits of small and medium enterprises need more rigour. We noted several areas where auditors must improve, such as using indirect methods of verification and considering the application of penalties more often.

Background and other observations

5.5 In December 2003, the government announced a major reorganization of some departments and agencies. The customs services operations of the Canada Customs and Revenue Agency were transferred to the newly created Canada Border Services Agency. The remaining organization operates as the Canada Revenue Agency.

5.6 The Agency defines small and medium enterprises as all self-employed individuals, small and medium-sized corporations, partnerships, and trusts. Small and medium enterprises include about 4.5 million taxpayers. Self-employed individuals accounted for almost 10 percent of the $90 billion in federal personal income tax revenue in 2003, while corporations with annual gross revenues of less than $15 million accounted for 36.5 percent of the $22 billion in federal corporate tax revenue that year. Over 60 percent of net goods and services tax (GST) and harmonized sales tax (HST) revenues, other than that collected by customs services on imported goods, comes from small and medium enterprises.

5.7 The small and medium enterprise sector is growing as the trend to self-employment increases. It is also the sector most at risk of participation in underground economy activities.

5.8 Computerized risk assessment systems, in conjunction with experienced auditors, are currently used to identify non-compliant taxpayers. Audits of taxpayers identified by the system as having high potential for non-compliance yield much higher reassessments than audits selected through other means.

5.9 The Agency has made changes to the computer-based risk criteria to select GST/HST refund claims for audit. In addition, it undertook several initiatives and pilot projects designed to strengthen GST/HST compliance. The validity of the risk criteria and the results of the new initiatives must now be measured.

5.10 The Agency has yet to complete a systematic review of the penalties provided in tax legislation to determine how effective these penalties are in improving compliance and achieving public confidence. We found that where the Agency reduced a certain penalty it applies to the late remittance of income taxes deducted from employee salaries by employers, it failed to get legislative authority to do so.

The Agency has responded. The Canada Revenue Agency agrees with all but one of our recommendations. In its responses, it provides background information and describes actions it will take to address the recommendations.

The Agency believes that one of our recommendations on better understanding compliance behaviour would divert resources from other activities and impose a burden on compliant taxpayers.

Managing Government
Using Financial Information

Chapter 6 Main Points

6.1 The government continues to improve financial information, including successful implementation of full accrual accounting in its 2003 summary financial statements. Making this change to the current year's summary financial statements was a significant accomplishment. The government should be proud of the results of this hard work and of the fact that the enhancements have established Canada as a world leader among national governments in financial reporting.

6.2 However, the adoption of accrual accounting in the summary financial statements was never intended as an end in itself, but rather as part of a wider initiative to improve financial management and control in the government. More work is still needed to resolve a number of outstanding issues.

6.3 Departments and agencies must now improve and use accrual financial information for their daily decision making and management and reporting practices; otherwise accrual accounting will be seen as something that is undertaken only to comply with initiatives or directives established by central agencies, such as the Treasury Board Secretariat.

6.4 The Office of the Comptroller General of Canada needs to lead this change by leveraging the momentum created by recent successes and by aggressively advancing financial management and control within the government. It also needs to develop a strategy to strengthen the financial capacity of senior financial positions and ensure that a strong departmental comptrollership capacity is established in all departments.

6.5 The government must finalize its study of accrual-based appropriations and budgeting at the departmental level. The Treasury Board Secretariat continues to state that this complex issue needs extensive study before a decision can be made, even though the government has been examining the issue for several years.

6.6 Departments and agencies must take additional and speedier action to correct weaknesses in their internal controls. Integrated and comprehensive internal control systems play a significant role in ensuring that high-quality financial information is available. After three years of examining internal control systems within departments and agencies, we continue to observe weaknesses similar to those we first identified in 2001.

Background and other observations

6.7 Complete financial information and strong internal controls are vital for achieving results for Canadians. The integration of financial and non-financial information into decision making, the establishment of effective financial information systems and controls throughout government, and the establishment of strong financial policies and procedures all lead to continuous improvements of stewardship in government.

6.8 Accrual financial information is an integral component of good financial information in government. Under accrual accounting, transactions and other economic events are recognized when they occur, rather than when cash or its equivalent is received or paid. Expenses are recorded in the period when the goods or services are consumed, revenues are recorded in the periods to which they pertain, and the multi-year economic benefits associated with capital assets are recognized in the period in which they are used.

6.9 Accrual financial information helps users appreciate the full financial scope of government—the resources, obligations, financing, costs, and impacts of its activities, including the costs of consuming assets over time. This more complete picture enables legislators to hold the government more accountable for the stewardship of its assets, the full costs of its programs, and its ability to meet short-term and long-term financial obligations.

6.10 Accrual financial information can also help improve decision making within departments. Managers will improve their focus on the stewardship of assets and liabilities under their control, consider the full periodic costs of providing services, and examine how the full range of costs might affect their use of public funds and assets.

6.11 The current operating environment within government encourages managers to focus on the amount of their original allotment of money left to spend (free cash balance) and not on the full accrual cost of their programs and activities. As a result, full cost information is not considered as important as cash expenditure information. This orientation by managers arises because, among other things, the basis of accounting used in the government's expenditure management system is not accrual accounting, and it is this system and its allotments against which most departmental and agency managers still feel the greatest accountability.

6.12 As well, the government's current model for departmental financial statements needs further improvement because it does not require recording and disclosure of some significant costs and liabilities and the valuation adjustment of some assets. In our view, without this information, departmental financial statements do not provide accurate and reliable information on departments' program costs and assets and liabilities.

The Treasury Board Secretariat has responded. The Secretariat has agreed with our recommendations, and its responses in the chapter describe current or planned actions to address the recommendations.

Managing Government

A Study of the Role of the Treasury Board and its Secretariat

Chapter 7

Overview

7.1 Following on the heels of the 1994–95 Program Review, the government has embarked on an ambitious agenda aimed at strengthening management across the federal public sector. The objective is to ensure that the key elements of good management are in place and that they are working well together.

7.2 Today's management agenda reflects a number of recurring themes in public administration, including how best to manage money, people, and information so as to

- preserve public trust;
- enhance economy, efficiency, and effectiveness; and
- ensure transparency and accountability.

7.3 The Treasury Board of Canada and the Treasury Board of Canada Secretariat play the lead role in developing and refining the government's management agenda and overseeing its implementation across departments and agencies. In performing that role, they face a number of significant challenges.

- **Setting the tone from the top**: maintaining interest in, and support for, the management agenda among ministers, senior officials, and parliamentarians.
- **Matching mandate and capacity of the Treasury Board and its Secretariat**: defining core responsibilities and having the right people in the right places with the right information to meet those responsibilities.
- **Strengthening department capacity**: ensuring that departments have the resources and tools to meet their management responsibilities.
- **Establishing and maintaining effective working relationships with departments**: recognizing that management responsibilities are shared between departments and agencies using communications, co-operation, co-ordination, and information-sharing to allow each to do its part.
- **Maintaining momentum**: paying attention to the full management cycle—strategic direction, planning, implementation, monitoring, and improving—over an extended period for each reform initiative.
- **Making best use of the tool kit**: determining and applying which of the various means available for influencing departments and their employees works best under what circumstances.

Background

7.4 This study provides Parliament with information on the key challenges that the Treasury Board and its Secretariat face in developing, refining, and implementing the federal government's management agenda. The study is a first step in the development of a longer-term audit plan for the Office of the Auditor General, covering key elements of the federal government's management agenda and the Treasury Board's role in them.

7.5 As the study neared completion, the prime minister announced a number of changes to the federal government's management practices. Those most relevant to this study are

- the Treasury Board and its Secretariat to focus on overseeing government expenditures, including the ongoing reallocation of spending from lower to higher priorities;
- a distinct Comptroller General's office in the Treasury Board Secretariat to help ensure that departments comply with the Board's expenditure and stewardship policies and to provide functional direction to department comptrollers;
- a new Cabinet committee on expenditure review to control spending and to align it with the evolving priorities of the government;
- a new agency for public service human resources management to improve human resources management in the public service and to implement the government's modernization initiative; and
- a transfer of responsibility for the Government On-Line initiative from the Treasury Board Secretariat to Public Works and Government Services Canada.

Report of the Auditor General of Canada to the House of Commons—March 2004

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Chapter 7 Managing Government: A Study of the Role of the Treasury Board and its Secretariat

2004

Report of the
Auditor General of Canada
to the House of Commons

MARCH

Chapter 1
National Research Council Canada—
Management of Leading-Edge Research

Office of the Auditor General of Canada

The March 2004 Report of the Auditor General of Canada comprises seven chapters, a Message from the Auditor General, and Main Points. The main table of contents is found at the end of this publication.

The Report is available on our Web site at www.oag-bvg.gc.ca.

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Ce document est également disponible en français.

© Minister of Public Works and Government Services Canada 2004
Cat. No. FA1-2004/1-1E
ISBN 0-662-36241-1

Chapter

1

National Research Council Canada

Management of Leading-Edge Research

All of the audit work in this chapter was conducted in accordance with the standards for assurance engagements set by the Canadian Institute of Chartered Accountants. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.

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National Research Council Canada
Management of Leading-Edge Research

Main Points

1.1 The National Research Council's (NRC) Governing Council is not fulfilling its duties to direct and control the work of the corporation through the President as required under the *National Research Council Act*. The Governing Council's responsibilities are not clearly defined and therefore are not well understood by the Council members. Thus, the Governing Council lacks important governance and accountability structures. As a result, there is no effective challenge to management plans and decisions. The *National Research Council Act* has not been updated to incorporate best practices for corporate governance, such as those in more recent legislation establishing a governing council.

1.2 The NRC needs to review its corporate mechanisms for setting priorities to avoid an imbalance between its research activities and available funding. Although it has had no core budget increase, it is currently launching several long-term initiatives that include major increases in infrastructure and staff. Meanwhile, the NRC is facing important challenges in funding most of its current activities.

Background and other observations

1.3 The NRC has earned international recognition in a broad diversity of scientific disciplines. It has a long history of making valuable scientific discoveries that contribute to the well-being of Canadians and others worldwide. While most of the research at the NRC is well managed, the leading-edge research funded predominantly by parliamentary appropriations is not subjected to a rigorous priority-setting framework at all institutes. If this situation continues, core competencies needed by the NRC to maintain Canada's competitive edge in scientific research worldwide could be eroded. In our view, the weakness in the priority-setting framework results from a failure to implement strategic plans and guidelines.

1.4 With an anticipated shortage of researchers looming, the NRC needs to be able to continue recruiting and retaining highly qualified researchers to be a leading research and development organization. To do so, the NRC must further develop its human resources management strategic direction, based on an assessment of the risks and opportunities to address key challenges in institutes. Further, it needs to have a coherent and comprehensive action plan to implement its strategic direction.

1.5 After seven years of collecting and reporting corporate performance data, the NRC is continuing to improve its performance measurement and reporting practices through a new corporate performance management framework. It now needs to strengthen and implement that framework and to address weaknesses in its Performance Report.

The National Research Council has responded. The National Research Council has accepted and agreed with all our recommendations and has provided individual responses. The responses include statements of actions already underway or planned to address the recommendations.

Introduction

1.6 Federal science and technology (S&T) activities play an important role in fulfilling government responsibilities in areas such as health and safety, protection of the environment, communications, and social and economic development. Statistics Canada estimates that the federal government spent $8 billion on S&T activities in 2002–03, of which $5 billion was for research and development (R&D).

1.7 A number of federal government departments and agencies are involved in R&D. Of these, the National Research Council (NRC) is the government's most comprehensive research arm. The NRC had expenditures of about $800 million in 2002–03, funded through parliamentary appropriations and government transfers (80 percent) and self-generated income (20 percent). For the same period, the NRC had just under 4,000 employees, as well as 1,200 guest workers from Canadian and foreign universities and public and private sector organizations. The NRC is larger than most Crown and departmental corporations in parliamentary appropriations received, number of employees, and number of buildings it owns and manages.

1.8 The NRC's mandate under the *National Research Council Act* is to "... undertake, assist or promote scientific and industrial research ..." that is in the national interest of Canada. The Act also sets out a specific mandate for the NRC related to "... the investigation and determination of standards and methods of measurements ...." *The Weights and Measures Act* sets out an NRC mandate for the calibration and certification of measurement standards. The NRC's vision, as stated in its Vision 2006 document published in April 2002, is "Recognized globally for research and innovation, [the] NRC is a leader in the development of an innovative, knowledge-based economy for Canada through science and technology."

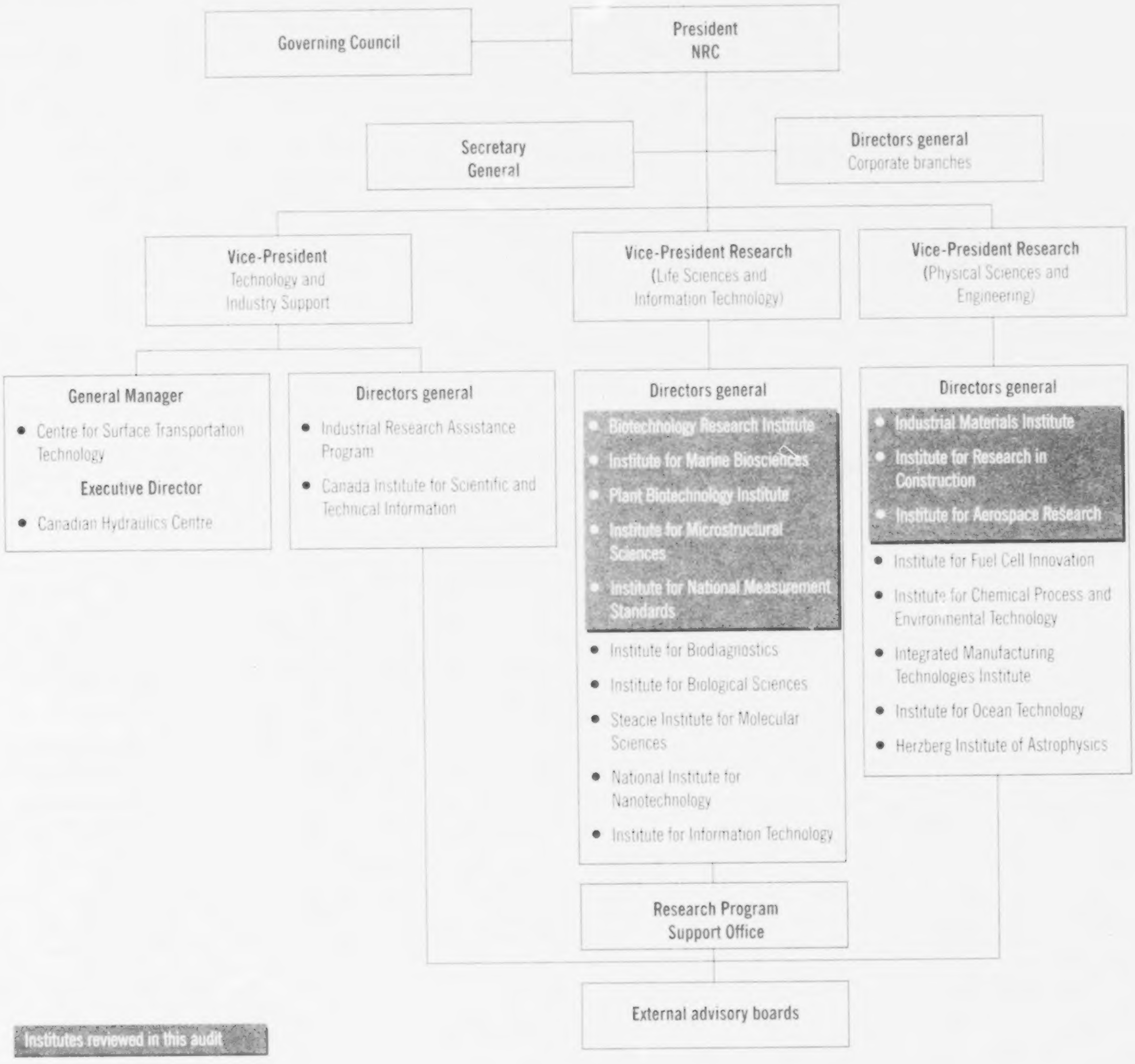
1.9 The NRC views its role as unique in the transfer of technology and dissemination of knowledge to industry and in enhancing innovation in Canada. It sees itself as a "public champion" for enabling Canadian companies and communities to develop sustainable knowledge-based growth while reinforcing connections to universities and industries. Unlike most other research organizations, the NRC institutes span the research spectrum, from exploratory to applied. They involve a wide range of sectors including aerospace, biotechnology, construction, information and communications, manufacturing, nanotechnology, and ocean engineering. Much of this research is done in collaboration with Canadian industry, universities, other government entities, and international organizations.

Nanotechnology—The building of objects on a scale that is measured in billionths of a metre.

1.10 The NRC has 18 research institutes and 2 technology centres across Canada, as well as the Canada Institute for Scientific and Technical Information and the Industrial Research Assistance Program (Exhibit 1.1). NRC institutes are located in nine provinces, each focussing on different areas of research, comprising anywhere from 60 to 320 staff, and reporting to the NRC corporate office through a director general and vice-president.

The technology centres are smaller in size and operate on a cost-recovery basis. In 2002–03, the NRC had expenditures of about $450 million for its institutes and technology centres, $100 million for its corporate services, and $245 million for other activities (see paragraphs 1.12–1.14).

Exhibit 1.1 **The National Research Council's organization**


Governing Council
President NRC
Secretary General
Directors general
Corporate branches
Vice-President
Technology and Industry Support
Vice-President Research
(Life Sciences and Information Technology)
Vice-President Research
(Physical Sciences and Engineering)
General Manager
Centre for Surface Transportation Technology
Executive Director
Canadian Hydraulics Centre
Directors general
Industrial Research Assistance Program
Canada Institute for Scientific and Technical Information
Directors general
Biotechnology Research Institute
Institute for Marine Biosciences
Plant Biotechnology Institute
Institute for Microstructural Sciences
Institute for National Measurement Standards
Institute for Biodiagnostics
Institute for Biological Sciences
Steacie Institute for Molecular Sciences
National Institute for Nanotechnology
Institute for Information Technology
Directors general
Industrial Materials Institute
Institute for Research in Construction
Institute for Aerospace Research
Institute for Fuel Cell Innovation
Institute for Chemical Process and Environmental Technology
Integrated Manufacturing Technologies Institute
Institute for Ocean Technology
Herzberg Institute of Astrophysics
Research Program Support Office
External advisory boards
Institutes reviewed in this audit

Source: National Research Council

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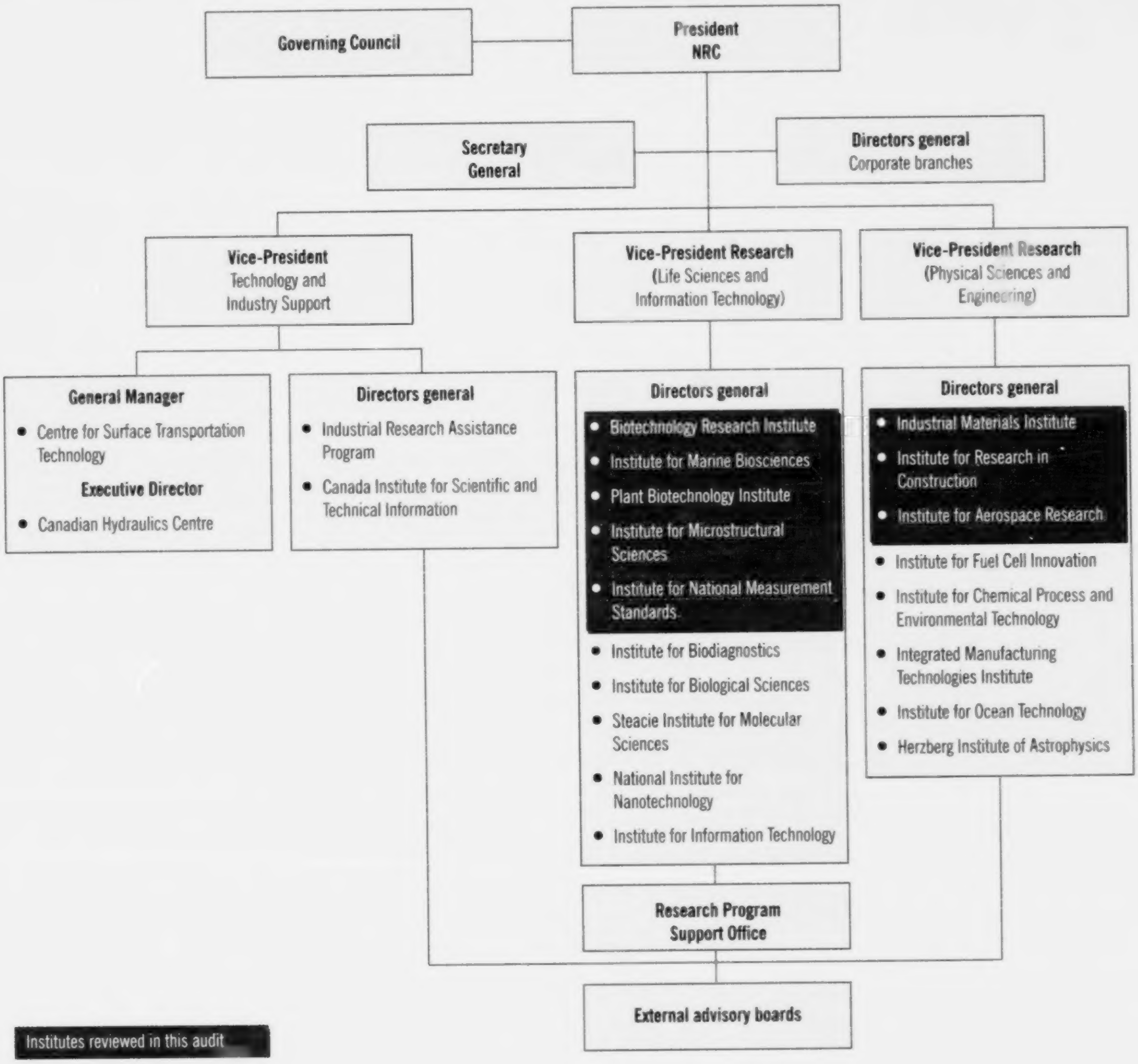

Governing Council
President NRC
Secretary General
Directors general Corporate branches
Vice-President Technology and Industry Support
Vice-President Research (Life Sciences and Information Technology)
Vice-President Research (Physical Sciences and Engineering)
General Manager
Centre for Surface Transportation Technology
Executive Director
Canadian Hydraulics Centre
Directors general
Industrial Research Assistance Program
Canada Institute for Scientific and Technical Information
Directors general
Biotechnology Research Institute
Institute for Marine Biosciences
Plant Biotechnology Institute
Institute for Microstructural Sciences
Institute for National Measurement Standards
Institute for Biodiagnostics
Institute for Biological Sciences
Steacie Institute for Molecular Sciences
National Institute for Nanotechnology
Institute for Information Technology
Directors general
Industrial Materials Institute
Institute for Research in Construction
Institute for Aerospace Research
Institute for Fuel Cell Innovation
Institute for Chemical Process and Environmental Technology
Integrated Manufacturing Technologies Institute
Institute for Ocean Technology
Herzberg Institute of Astrophysics
Research Program Support Office
External advisory boards
Institutes reviewed in this audit

Source: National Research Council

Contributions of the National Research Council

1.11 The NRC has a long history of making valuable scientific discoveries that contribute to the well being of Canadians and others worldwide. It has earned international recognition in a broad diversity of scientific disciplines. It is a key player in maintaining Canada's competitive edge in the knowledge-based economy.

1.12 The Canada Institute for Scientific and Technical Information (CISTI) is Canada's largest publisher and disseminator of scientific, technical, and medical information. In 2002–03, CISTI spent about $53 million providing just under a million documents to Canadian academics, industries, governments, and medical professionals and others around the world.

1.13 The Industrial Research Assistance Program (IRAP) is intended to stimulate wealth creation for Canada through technological innovation in Canadian small and medium-sized enterprises. It does this through technical and business advice, financial assistance, access to business information, contacts, and national and international networks. In 2002–03, IRAP spent $151 million helping 12,000 private sector firms across Canada. These costs included $95 million in IRAP contributions.

1.14 Other NRC 2002–03 expenditures included $41 million in contributions for the Tri-University Meson Facility.

1.15 The NRC actively encourages the creation of new research-based enterprises from its laboratories. It reports that it has created 55 new companies in a variety of sectors since 1995 and that this has generated employment for about 500 Canadians and cumulative private investments of $250 million. These companies were formed either by NRC employees (after having resigned or taken a leave of absence) or by non-NRC principals using NRC technologies. As well, a number of specialized agencies and services have grown out of the NRC over the years, including Atomic Energy of Canada Limited, the Medical Research Council (now known as Canadian Institutes of Health Research), the Natural Sciences and Engineering Research Council, and the Canadian Space Agency.

Some National Research Council discoveries and successes

- Developed a highly effective vaccine against meningitis-C, a disease that kills 10 percent of its victims and can cause permanent brain damage, deafness, or mental retardation in survivors. This vaccine has so far generated royalty payments to the NRC of about $10 million.
- Helped develop canola, a crop worth over $2 billion to Canadian farmers.
- Developed a successful prototype of a "single spin" transistor made from a quantum dot. This was an important advance because current technology is reaching its limit.
- Isolated antibodies that target tumours, as part of developing novel immunotoxins that kill cancer cells.

Focus of the audit

1.16 Our audit objectives were

- to assess the National Research Council's systems and practices for setting strategic direction for its scientific research activities, including its corporate governance and accountability structure; and
- to determine whether it managed these activities in a way to maximize results and whether it measured and appropriately reported the results and impacts of its efforts.

The National Research Council has developed advanced imaging techniques and equipment to diagnose human disease and aid in treatment.

1.17 We assessed the significance, risks, auditability, and interest to Parliament of the NRC's activities and programs. We identified four lines of enquiry for examination: corporate governance and setting of corporate strategic direction, research management at the institute level, human resources management, and performance measurement and reporting.

1.18 Some quantitative information in this chapter is based on data provided by the NRC. We have assessed these data through a process of analysis, comparison, and discussion. Unless otherwise indicated in this chapter, these data should be treated as unaudited.

1.19 Our audit did not include a review of the quality of the NRC's research. Program evaluations to assess whether program objectives are being met are the responsibility of the NRC. Since 2001, the NRC has conducted five evaluations—the Biotechnology Program (delivered by five NRC institutes), the Institute for Chemical Process and Environmental Technology, the Industrial Research Assistance Program, and two initiatives supported by the NRC (the Tri-University Meson Facility and the Canadian Technology Network). Further details on the audit are found at the end of the chapter in **About the Audit**.

Observations and Recommendations

Corporate governance

Governance and accountability regime does not allow effective challenge of management decisions

1.20 Corporate governance refers to the process and structure for overseeing the direction and management of a corporation so that it carries out its mandate and objectives effectively. Good corporate governance is important to maximize performance, prevent financial losses, and help to achieve the corporate mandate.

1.21 The National Research Council (NRC) is a departmental corporation, listed under Schedule II of the *Financial Administration Act*. The President of the NRC is the Chief Executive Officer of the corporation and Chair of the Governing Council.

1.22 Section 3.(1) of the *National Research Council Act* establishes ". . . a Council, to be called the National Research Council of Canada, consisting of a president and not more than twenty-one other members . . . ." However, the legal title of the corporation, including all of the researchers, other staff, and managers, is also the National Research Council of Canada. In order to distinguish between these two groups, the NRC uses the term "Governing Council" when referring to the President and the 21 external members appointed by the Governor in Council. For the purposes of this section, we will distinguish between the Governing Council and the corporation.

1.23 The Act provides significant duties and powers to the Governing Council. Section 4 specifies its duties as having "charge of such matters affecting scientific and industrial research in Canada as may be assigned to it by the Governor in Council." Section 5.(1)(b) grants the Governing Council the power to "control and direct the work of the Council [corporation] through the President." The key responsibilities we normally associate with controlling and directing the work of an organization include approving corporate strategic plans, monitoring progress against those plans to achieve stated objectives, approving budgets, and approving accountability reports or annual reports.

1.24 The responsibilities of the Governing Council are very broadly defined by the Act. We expected to find a resolution setting out the terms of reference by which the Governing Council would fulfil its mandated responsibilities, including any important distinctions between the role of the President as Chair of the Governing Council and as Chief Executive Officer of the corporation. Management has advised us that no such terms of reference exist and that the Governing Council conducts business in accordance with the National Research Council of Canada General By-law, approved by the Governor in Council in December 1990. The by-law is administrative in nature and deals essentially with the scheduling and conduct of Governing Council meetings; it is silent on the responsibilities of the Governing Council in fulfilling its mandated role under the Act.

1.25 We expected that the Governing Council would have established a structure and defined its requirements for management information, including planning, financial, and operational information, to make informed decisions about the strategic direction of the corporation and to provide an effective challenge of management decisions. We found no evidence of specific requirements for management information going to the Governing Council. However, management does provide institute strategic plans and other relevant corporate proposals to the Governing Council for approval. We noted that the Governing Council lacked important structural tools to assist it in providing its oversight function, such as the use of an audit committee or a human resources management committee.

1.26 **Role of Governing Council is unclear.** We attended two meetings of the NRC Governing Council, in June and October 2003. In addition, we interviewed six members of the Executive Committee of the Governing Council to obtain their views on the role that they and their colleagues on the Council are mandated to perform under the *National Research Council* Act. We also interviewed the President of the NRC to obtain his perspectives.

1.27 Our discussions revealed a lack of clarity among Governing Council members about the role of the Governing Council—that is, whether it is simply advisory in nature to the President or whether it includes the obligation to direct and control the work of the corporation through the President. The Governing Council is currently operating primarily as an advisory body. The NRC has advised us that, according to its research, the role of the Governing Council as an advisory body has not changed over the past three decades. We are concerned about this apparent inconsistency with the enabling legislation, and believe that it has led to the absence of the key Governing Council governance initiatives and structure noted earlier. A review is needed to reconcile the gaps between the statutory role of the Governing Council, which provides the expectation of oversight of the corporation's operations, and its current practices.

1.28 **Enabling legislation has not been updated.** The NRC's enabling legislation was first enacted in 1917; the most recent amendments related to the Governing Council's powers were enacted in June 1979. We reviewed the *Canadian Institutes of Health Research Act*, enacted in April 2000, as an example of the government's current practices when establishing a Governing Council. Like the NRC, the Canadian Institutes of Health Research (CIHR) is a departmental corporation listed under Schedule II of the *Financial Administration Act*.

1.29 The *Canadian Institutes of Health Research Act* is similar to the *National Research Council Act* in that it confers on the CIHR's Governing Council the mandate to manage the affairs of the corporation. However, it also differs from the *National Research Council Act* in important areas, such as providing greater clarity in the intent of its provisions, as follows:

- It establishes both a corporation and a governing council and makes a clear distinction between the two entities.
- It clearly stipulates the powers and functions of the corporation and the responsibilities of the Governing Council.
- It makes the Governing Council explicitly responsible for managing the corporation and stipulates the following key responsibilities: developing the CIHR's strategic directions, goals and policies; evaluating its overall performance, including achievement of its objective; approving budgets and funding for research and other expenditures; and establishing policies for dealing with collaborative partnerships.
- It makes the Governing Council responsible for establishing, maintaining, and terminating Institutes of Health Research, including a periodic review of the mandate and performance of each institute.

1.30 The NRC must ensure that its Governing Council has the necessary governance mechanisms in place to fulfil its mandated role. In order for the Governing Council to fulfil the role to "control and direct the work of the Council," it will be essential to ensure that members have the appropriate skills and experience. In reviewing the role of the Governing Council, the NRC could consider the best practices for corporate governance as reflected in more recent enabling legislation for departmental corporations.

1.31 **Review of corporate senior management structure is needed.** The NRC's review of the Governing Council's structure and governance mechanisms would also provide a timely opportunity to review its corporate senior management structure. Crown corporations with the complexity, staff, and budget comparable to those of the NRC normally have vice-presidents of finance and human resources management. While the NRC's research activities are headed by three vice-presidents, the functions of corporate services, finance, and human resources management are headed by directors general reporting to the President. It would be appropriate for the NRC to review its corporate senior management and accountability structures.

1.32 **Recommendation.** The National Research Council (Governing Council) should define its role to meet its assigned responsibilities under the *National Research Council Act* and should put in place the necessary governance mechanisms to implement that role.

National Research Council's response. While recognizing the historical perspective that the Governing Council has functioned essentially as an advisory body for decades, the National Research Council accepts this recommendation and will work with the Governing Council to more clearly define the Council's role. The NRC will also ensure that it has the systems and structures in place to provide the necessary organizational support to fulfil that role.

1.33 **Recommendation.** The National Research Council should include a review of its corporate senior management structure to ensure appropriate accountability within the corporation and to a restructured Governing Council.

National Research Council's response. The National Research Council accepts this recommendation and has already taken steps to add the Director General of Finance and the Director General of Human Resources to the Senior Executive Committee. A further review of the senior management structure will be undertaken in 2004, after the arrival of the new President of the NRC.

1.34 **Recommendation.** The National Research Council should seek advice on what remedies are available to it under the *National Research Council Act* to facilitate the realignment of the Governing Council's role, including ensuring that it has the right profile of Council members and, if appropriate, proposing amendments to the legislation to better reflect best practices for governance of departmental corporations.

National Research Council's response. The National Research Council accepts this recommendation and will strike a task force, involving Governing Council members, to follow up on this recommendation and will consult the appropriate individuals in the Privy Council Office and the Department of Justice Canada to develop a proposed course of action.

Setting corporate strategic direction

1.35 Governance within the NRC involves both internal staff and external representatives (Exhibit 1.1). The NRC Governing Council includes the President and up to 21 other members. NRC management's Senior Executive Committee is composed of the President (Chair), the three vice-presidents, and the Secretary General; it acts as the main internal decision-making body in all matters pertaining to the NRC's operations. Each NRC institute, as well as the Canada Institute for Scientific and Technical Information and the Industrial Research Assistance Program, is headed by a Director General and has an external Advisory Board that provides strategic advice on program and policy matters relevant to the institute or program. Both the Governing Council and advisory boards are composed of external representatives, mostly from private industry and academia.

Good practices in developing vision

1.36 Setting corporate strategic direction is one of the key activities of any organization; it allows the organization to transform its vision into a corporate strategy, including the identification of future priorities based on an assessment of opportunities, risks, and potential resources.

1.37 We expected the NRC to ensure that its vision and priorities were linked to its mandate and the government's agenda, and established after consultation with key stakeholders.

1.38 Except for the human resources management component, the NRC followed good practices in preparing its current vision document, *Vision 2006: Science at work for Canada*. A February 2002 internal audit concluded that Vision 2006 reflects government direction and that significant environmental scanning and consultation allowed the NRC to identify many opportunities for it to contribute its expertise to improve technological solutions for Canadians. The NRC's vision document outlines five strategic pillars and related corporate goals, strategies, and desired outcomes for a five-year period (2001 to 2006). Our review indicates that the vision is closely aligned with the federal government's March 1996 science and technology strategy and February 2002 innovation strategy.

Need to review mechanisms for setting priorities

The National Research Council's original headquarters on Sussex Drive in Ottawa.

1.39 We expected the NRC to ensure that its strategic decisions and priorities were based on a thorough analysis of its operating environment, options, risk, and future impacts, and reflected in the allocation of internal funds. We also expected the NRC to periodically reassess the value and continuing relevance of its research areas.

1.40 We are concerned that the NRC's current and future expansion could negatively affect its overall effectiveness, and we question how long the NRC can continue to expand with no increase to its core budget. The combined effect of the following factors makes selecting priorities and assigning scarce resources an increasing challenge for the NRC:

- The NRC is facing important resourcing challenges.
- There has been a significant increase in long-term research activity, including major expansion of facilities, with no core budget increase.
- The NRC does not have a regular and rigorous process to synthesize its priorities and make strategic decisions based on a realistic assessment of capacity.
- The NRC's last comprehensive review of all its research areas that resulted in a refocussing of research efforts was in 1995; the NRC has limited flexibility in reallocating internal funds.

1.41 **The NRC faces important resourcing challenges.** The NRC is involved in a wide variety of research areas and plans to add more. Although some specific research-related initiatives have recently been funded through appropriations (for five to six years), the related increase in staff and infrastructure puts additional pressure on the NRC's corporate services. Its vision includes desired strategic outcomes that will involve further increases in research activity. Meanwhile, the NRC is facing important challenges in funding ongoing operations, including maintaining its infrastructure and state-of-the-art equipment, paying increasing utility costs and taxes, and hiring staff.

1.42 Unlike federal government departments, the NRC must bear the cost of maintaining its buildings, including utility costs and payments in lieu of taxes. In 2001, it submitted a long-term capital plan to the Treasury Board Secretariat that identified a cumulative shortfall of $308 million by 2005. The plan identified total requirements, net of yearly capital appropriations, for maintenance and repairs to the NRC's 181 buildings (60 percent of which were constructed over 30 years ago), upgrading of research equipment, and new buildings and equipment. The NRC has since received funding for specific research-related initiatives, which included coverage of about half of the capital plan shortfall. We estimate the shortfall to be about $150 million now.

1.43 Although the NRC has implemented a number of energy-saving measures over the years, increasing utility costs and payments in lieu of taxes are having a negative impact on funds available for research. In the last four years, these annual costs have increased substantially—from $19 million in 1998–99 to $31 million in 2002–03.

1.44 The NRC was facing a tight financial situation during 2003–04, due to higher than expected expenditures and lower revenue. Senior management had to take a number of measures, including a 1.5 percent budget cut across the organization. In addition, some institutes may be at a crucial point in being able to ensure continuing operations. We found evidence that some institutes had previously been unable to fully accomplish their stated priorities because of a lack of funding to hire additional qualified staff.

The new National Research Council Aluminium Technology Centre in Ville Saguenay, Quebec

1.45 **Increased long-term research activity, including major expansion of facilities, launched with no core budget increase.** Increased research activities at the NRC have resulted from additional appropriations of $430 million up to 2006–07 for targeted projects and from investments from other federal government agencies, provincial governments, universities, and industry. A large number of major capital projects have recently been completed, are ongoing, or are planned. Since 2000–01, the number of staff has increased by 470 (14 percent), and more staff will be needed once the new institutes and research centres are fully operational.

1.46 The new projects and ongoing or planned initiatives include two new research institutes—the National Institute for Nanotechnology in Edmonton, Alberta, and the Institute for Nutrisciences and Health in Charlottetown, P.E.I., and 10 new Industry Partnership facilities (attached to an NRC institute and used to house start-up companies). There are also several new research centres or locations, including the following:

- Aluminium Technology Centre in Ville Saguenay, Quebec
- Aerospace Manufacturing Technology Centre in Montréal, Quebec
- Canadian Photonics Fabrication Centre and Gas Turbine Environmental Research Centre in Ottawa, Ontario

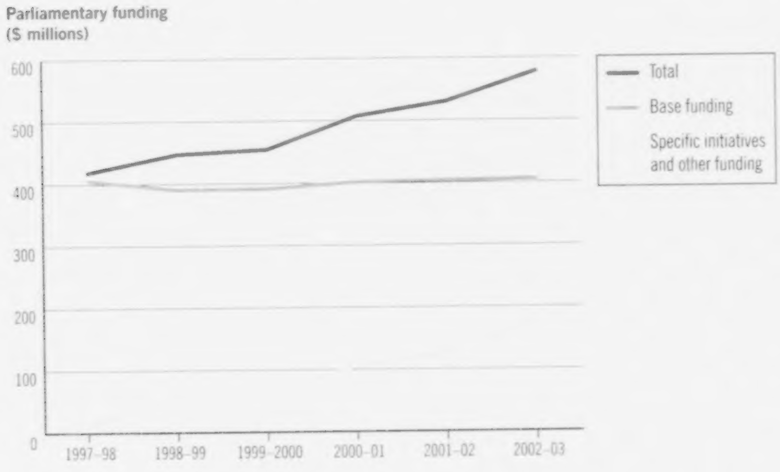
- E-business research centres in Fredericton, Moncton, and Saint John, New Brunswick and Wireless Systems in Sydney, Nova Scotia
- Centre for Sustainable Urban Infrastructure in Regina, Saskatchewan
- Language Technology Research Centre in Gatineau, Quebec

1.47 We reviewed four of the recent strategic initiatives to assess the appropriateness of the decision-making process and the elements considered (see case study on page 13, Four strategic initiatives by the National Research Council). We found that all four initiatives are linked to the NRC's mandate and the government's agenda, that there were good consultations with key stakeholders, and good analyses of options, risks, and partnership opportunities. However, there was no assessment of the potential financial implications of these initiatives on the NRC's current operations.

1.48 These initiatives are all expected to become key elements of the NRC's future research activities and will likely require ongoing operational funding for decades to come. However, the funding received for these initiatives was for five to six years, with very little commitment from the government for future operational funding.

1.49 In recent years, the NRC has received additional parliamentary funding for specific initiatives but has had no increase in its base funding for ongoing operations since at least 1997–98 (Exhibit 1.2). Although it has been able to benefit from increased self-generated revenues through increased fee-for-service activities and collaborative partnerships, it expects future increases of these revenues to be limited. The funding uncertainty puts the long-term sustainability of current and new initiatives at risk.

Exhibit 1.2 The National Research Council has had almost no increase in its base funding since 1997-98



Source: Public Accounts of Canada and the National Research Council

Four strategic initiatives by the National Research Council

The purpose of this case study was to determine whether the National Research Council's (NRC) recent research initiatives were linked to its mandate and the government's agenda; established after consultation with key stakeholders; and based on thorough analyses of its operating environment, options, risks, and future impacts.

We reviewed four NRC strategic initiatives carried out in recent years:

- the creation of a new research institute—the National Institute for Nanotechnology in Edmonton, Alberta
- the creation of another new research institute—the Institute for Nutrisciences and Health (Bioactives) in Charlottetown, P.E.I.
- the launching of a new research area—E-business in Fredericton, Moncton, and Saint John, New Brunswick
- the creation of the Canadian Photonics Fabrication Centre in Ottawa, Ontario

Four strategic initiatives linked to the NRC's mandate and the government's agenda. There is a reasonably clear and direct link between the four new initiatives and the NRC's strategic objectives and vision, and with the government's 2002 Innovation Strategy.

In establishing the National Institute for Nanotechnology in Edmonton and the Canadian Photonics Fabrication Centre in Ottawa, the NRC first identified the key technology areas to pursue based on an analysis of their importance and the need for the NRC to be involved. It then identified the most suitable location, based on local capabilities, funding options, receptor characteristics, and other key success factors.

In establishing e-business in New Brunswick and Bioactives in P.E.I., the NRC indicated that government decisions had a strong impact on the development sequence. The Cabinet Committee for the Economic Union approved the NRC's technology cluster concept in November 1999. A technology cluster refers to a significant concentration of high-technology companies gathered around a nucleus of a major research institution, such as a university or a government research laboratory. According to the NRC, the federal government then said that it would provide funding to the NRC if it developed projects in the Atlantic region. Therefore, the decision on general location came first (from the government), and then the choice of technologies and the specific cities (led by the NRC through consultations with stakeholders and analysis). The NRC returned to the government with proposals for e-business in New Brunswick and Bioactives in P.E.I., and these were accepted.

Good consultations with key stakeholders. The NRC made a significant effort to consult with key stakeholders to discuss the characteristics and directions of the proposed clusters. Stakeholders included federal government departments and agencies, provincial and municipal governments, universities, Canadian national experts, and local businesses.

Good analyses of options, risks, and partnership opportunities but no assessment of the potential financial implications on the NRC's current operations. The NRC conducted proper analyses of options, risks, and partnership opportunities for all four strategic initiatives. It determined that the four new initiatives would contribute positively to the research activities of other existing NRC institutes. However, it did not assess the potential financial implications on its current institutes, programs, and branches.

1.50 **The NRC lacks a regular and rigorous process to synthesize its priorities.** The NRC has chosen not to have a corporate business plan. Instead, it relies on Vision 2006 to document key corporate goals and strategies and on five-year institute strategic plans to provide more detailed information on how each institute intends to accomplish the corporate vision. Institutes, programs, and branches also prepare yearly planning outlooks. However, the NRC has no overall process for synthesizing priorities and making related decisions based on a realistic assessment of capacity.

Need for a comprehensive review of research areas

1.51 We expected the NRC to periodically review the value and continuing relevance of all its research areas, including its current institutes. This would allow it to set priorities for its activities at the highest level and identify if trade-offs were necessary based on available funding. We also expected the NRC to periodically review its allocation of funding to institutes, programs, and administrative branches. This would allow it to ensure that its internal funding of activities reflected its current priorities.

1.52 The NRC conducted a comprehensive review of the value and continuing relevance of all its research areas as part of the federal government's Program Review in 1995. At that time, it realigned its programs and services. In 1998, it also converted the research focus of one of its institutes to redirect efforts and facilities to the emerging fuel cells initiative.

1.53 The NRC has practices that help fine-tune the research focus of its institutes. It conducts program evaluations and independent peer reviews of its institutes and programs. All institutes also prepare strategic plans once every five years, which are vetted by the NRC's senior executives and approved by the Governing Council. A number of research activities have been reoriented as part of this process and other processes. However, as discussed in the section "Research management at the institute level," we found that lower-level reviews of certain institute activities are inadequate. Two of eight institutes audited had poor systems and practices for periodically reviewing the value of ongoing research projects.

1.54 In 1999–2000, the NRC conducted what it referred to as the Performance Review and Reallocations Exercise. It is our understanding that the objective of this exercise was to review institutes' past performance and future directions in order to ensure, through budget reallocations, an appropriate balance of funds across the organization. The NRC has indicated that this was a very comprehensive review, but we were unable to confirm this based on the limited documentation provided. The review identified differences among institutes in terms of past performance results (ratings varied from adequate to excellent) and their potential to contribute to science, technology, and wealth creation for Canada. We would have expected such a review to result in appropriate refocussing of research efforts, with priority given to those areas with the most potential. However, because the NRC felt that the 1999 budgets represented a threshold to sustaining research activities and scientific integrity in each institute (as established during Program Review), decreases beyond two percent could not be justified.

1.55 We noted instances of fine-tuning of the research focus of some institutes, including small budget adjustments. However, given the important resourcing challenges facing the NRC, it would benefit from conducting a high-level systematic and transparent review of the value and continuing relevance of all its research activities. Such a review would identify the need for any major trade-off decisions based on available funding, including the need to terminate some research activities if warranted.

1.56 **Recommendation.** The National Research Council should develop a corporate business plan that sets clear priorities, objectives, and strategies based on its financial capacity. As part of this process, it should develop a rigorous priority-setting mechanism and conduct a comprehensive review of the value and continuing relevance of all of its activities, including refocussing of research efforts as appropriate.

National Research Council's response. Through its Vision 2006, the National Research Council has a strong strategic-level vision for the organization that is linked through strategic and operational plans at the institute level to the business of the NRC. The NRC will build on its existing strategic strengths at the corporate level, and it will develop and implement a more formal corporate business planning system, including an annual rolling three-year business plan. The NRC also accepts the need for a periodic comprehensive review of its programs, and it will undertake to define a process that will achieve the desired result, taking into consideration the unique characteristics of a research organization.

Research management at the institute level

Research funded primarily by appropriations provides significant contributions

1.57 Research is the NRC's primary activity. The NRC does much of its research in partnership with industry, other governments, and educational institutions in Canada and abroad. An NRC internal audit of partnership practices for collaborative research completed in 2002 concluded that, in general, NRC institutes managed partnerships well. The audit included a review of institute awareness of partnership opportunities; the links with the NRC's mandate and vision; the documentation of project objectives, risks, success factors, and resourcing; and project management practices. We therefore focussed on other research projects that were funded predominantly by parliamentary appropriations and managed solely by the NRC. Those projects mostly involve leading-edge research of no immediate commercial interest and innovative new approaches that allow NRC researchers to maintain their core capabilities and leadership in a highly competitive knowledge-based economy.

Leading-edge research at the National Research Council spans a broad spectrum, including communications security.

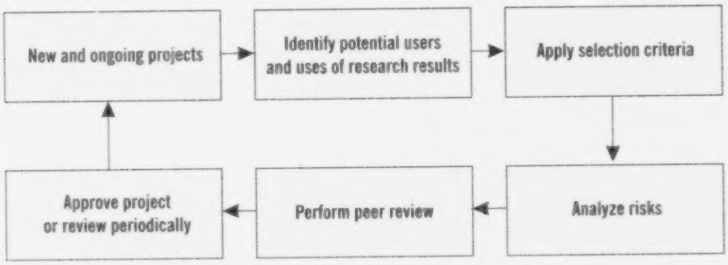
1.58 For our review, we selected 43 medium- to high-dollar value research projects and/or programs in eight NRC institutes. We selected institutes with a view to ensuring a good representation of geographic locations, disciplines, and size.

1.59 The NRC was unable to provide information on the total number of research projects it was conducting or on the number and costs of research projects totally funded by parliamentary appropriations. Management explained that its research programs are a complex mix of basic research, collaborative research with universities and industry, and fee-for-service work, and it is difficult to identify projects funded solely by appropriations. In the absence of such information, we were unable to assess the relative importance of these research projects compared with those involving partnership funding. However, while the NRC has moved toward more partnership programs in recent years, projects funded primarily by appropriations continue to provide a significant contribution to the NRC's research activities. Indeed, the new scientific discoveries of today will lead to the new products and industries of tomorrow.

Some institutes need a better framework for setting priorities

1.60 We expected the NRC to have an appropriate priority-setting framework (Exhibit 1.3) for selecting, reviewing, and terminating research projects so that only those offering the best value for Canada were retained. At the same time, we acknowledge the need for flexibility so that the framework is applied with a level of rigour commensurate with the estimated cost and risk of research activities.

Exhibit 1.3 A priority-setting framework for research projects


New and ongoing projects
Identify potential users and uses of research results
Apply selection criteria
Analyze risks
Perform peer review
Approve project or review periodically

1.61 We found evidence of some very good practices. All institutes in our sample have mechanisms in place to ensure that research activities are focussed on pragmatic problems. Researchers we spoke to were passionate about their research, knowledgeable about their science, and linked to the scientific community. Many are adjunct professors at universities and active members of the scientific community nationally and internationally. Most researchers are involved in industrial partnership research activities and this has resulted in an enhanced awareness of the needs of the users. Virtually all researchers we interviewed had a clear vision of the benefits of their research for Canadians.

1.62 Further, two institutes in our sample review all their research activities (new initiatives, ongoing projects, and related activities) on a cyclical basis, allowing all projects to be scrutinized collectively in a transparent and informed context.

1.63 The NRC's systems and practices do not provide assurance that only research projects offering the best value for Canada are retained. Of the eight institutes that we visited, two had good to excellent practices in almost all areas related to selecting, reviewing, and terminating research projects; four had a mix of good and weak practices; and two had major weaknesses in their priority-setting frameworks. We also found that there was a good priority-setting framework for the Genomics and Health Initiative research projects that are conducted in a number of NRC institutes.

1.64 The NRC has mechanisms in place to ensure that institute strategic plans are in line with the corporate vision. All institutes complete five-year strategic plans that are reviewed by the NRC's senior executives and approved by the Governing Council. These documents outline the institute's roles and research priorities for attaining the NRC's vision and corporate goals. However, most of the institutes visited lack documentation such as records of decision and rationale for approving specific projects or programs. Thus, we were unable to determine if activities at the project/program level were consistent with the NRC's vision and goals.

1.65 We found that certain research management practices varied considerably among institutes; for the most part, they are a function of institute preference rather than a specific rationale. While some met our expectations, many fell short. Weaknesses and possible consequences of research management practices are identified in Exhibit 1.4.

Exhibit 1.4 Framework for setting priorities: Weaknesses and possible consequences

Weakness	Possible consequence
Four institutes had no or vague criteria for selecting or reviewing their research projects.	Projects may not be aligned with the National Research Council's (NRC) corporate objectives and desired outcomes.
Four institutes had either no peer review practices or no independent third-party review.	Objectivity and opportunity for additional expertise may be lost.
At the institute level, risk analysis was more intuitive than formal. For the research projects, factors were not considered together and equipment was not assessed for possible failure.	Some important risks may be overlooked. The NRC has identified maintaining leading-edge equipment as an overall risk to the organization.
In one institute, project approval was done by a single manager with little consultation and documentation.	The best research projects may not be selected.
Two institutes had poor practices for reviewing ongoing research projects.	Projects may continue beyond what is necessary.

1.66 We recognize that one of the challenges of research activities is to find an appropriate balance between oversight and scientific creativity. However, with research projects at the core of the NRC's vision and strategic objectives, a good priority-setting framework in institutes is important. This framework should include consideration of the NRC's vision and goals, potential uses and users of the research, risks, and views from peers. It should also include a rigorous project approval process and a periodic review of the value of projects. We found that two of the eight NRC institutes visited and the GHI research projects had such frameworks.

1.67 **Recommendation.** The National Research Council should improve the priority-setting framework in its institutes so an appropriate process is in place to ensure that only research projects offering the best value for Canada are retained.

National Research Council's response. The National Research Council strives to ensure that research projects are selected on the basis of their scientific merit, their contribution to national science programs, and their value for Canada. The NRC is therefore committed to developing a priority-setting framework for its long-term research based on institute best practices identified in the audit report. It will focus on the life-cycle practices for selecting, reviewing, and terminating research projects. The NRC will also identify best practices in the NRC and elsewhere in documenting decisions related to project selection, approval, and termination and will reflect these in the proposed priority-setting framework.

Institutes lack relevant documentation of key decisions

1.68 Our findings on research management are based in large part on interviews with 63 NRC institute staff members of various hierarchical levels, including directors general, directors, project leaders, and researchers. Although we also reviewed NRC documents related to the research activities selected, documentation of project management processes and decisions was lacking. Key decisions such as project selection, approval, termination, and major shifts in project direction were generally not well documented.

1.69 Many institutes rely heavily on the collective experience and knowledge of staff for project selection and management. As the NRC expands into various new areas and as senior managers and researchers retire, there is a strong risk that key corporate knowledge and the capacity to share information and processes will be lost.

1.70 Further, the NRC's mechanisms for handling project information do not allow it to analyze and reconfigure data to provide fundamental information, such as compilation of all NRC projects, cost of a project within a given program, and linkages between file systems. We also noted that the information was scattered and that mechanisms to cross-reference and integrate information were weak.

1.71 **Recommendation.** The National Research Council should clearly document key decisions related to research project selection, approval, termination, and major shifts in project direction to ensure that important corporate knowledge is not lost.

National Research Council's response. The National Research Council strives to ensure that research projects are selected on the basis of their scientific merit, their contribution to national science programs, and their value for Canada. The NRC is therefore committed to developing a priority-setting framework for its long-term research based on institute best practices identified in the audit report. It will focus on the life-cycle practices for selecting, reviewing, and terminating research projects. The NRC will also identify best practices in the NRC and elsewhere in documenting decisions related to project selection, approval, and termination and will reflect these in the proposed priority-setting framework.

Human resources management

1.72 The NRC aims to be a leading-edge organization in research and development. Its objective is to be a major innovator in human resources management. Over the last three years, the NRC has invested considerable effort to develop and implement a strategic approach to its human resources management (HRM).

Researchers, students, and guest workers conduct biotechnology-related research in National Research Council facilities.

1.73 The NRC operates in an environment with fierce competition for new resources. It competes with industry and universities at the national and international levels while operating in a government context. Tailoring a strategic HRM approach that can support the strategic plans of more than 25 institutes, programs, and branches is a huge challenge.

1.74 The NRC cannot simply apply strategic management practices from the private sector. Generally, some of the core requirements to manage human resources include an established strategic planning process, the development of an HRM plan supporting the strategic business plans, and the involvement of the Human Resources Branch as a strategic partner. In our opinion, the NRC is moving in the right direction in implementing this emerging trend.

1.75 We looked at how the NRC developed and put in place its expected HRM strategic outcome, goals, plan, and priorities to achieve Vision 2006.

Strategic direction for Vision 2006 needs to be developed further

1.76 **More extensive environmental analysis is needed.** We expected to see a formal HRM environmental analysis that captures future-oriented and critical information on the NRC's potential HRM challenges for the next five years. The analysis is intended to ensure the relevance of the long-term HRM strategic outcome, goals, plan, and priorities.

1.77 In finalizing its Vision 2006 document in 2001, the NRC added a human resources management strategic outcome, "Outstanding People—Outstanding Employer." However, this was included without a rigorous consultation with institutes, programs, and branches, and without an HRM environmental analysis of the constituencies of the NRC to identify risks and opportunities.

1.78 In support of its Vision 2001, the NRC did a comprehensive job of developing competencies, which are used for staffing and in some cases for learning and performance management. However, with the new Vision 2006, we found very little future-oriented information available from the NRC's institutes, programs, and branches. For example, the following information was lacking:

- the types of competencies that are now obsolete and the types of new competencies required to implement the five-year institute strategic plans (based on the NRC competency model);
- the availability of and demand for needed competencies in the labour market;
- clear information, at the institute level, on compensation competitiveness for researchers in comparable organizations; and
- the impact of the financial situation in institutes, programs, and branches on attracting and keeping highly qualified people.

1.79 In January 2001, the NRC put in place a Human Resources Management Steering Committee to oversee HRM initiatives. The committee is composed of a vice-president, some directors general, some directors, and the Director General, Human Resources Branch. Although this committee provides input on behalf of stakeholder representatives, the Human Resources Branch needs to capture comprehensive strategic thinking and insights within institutes, programs, and branches—to determine what should be addressed and in what order to support the strategic plans. At the time of our audit, the Human Resources Branch had not collected this information.

1.80 We noted that institute managers we interviewed possess a good knowledge of their external and internal human resource environment, but their knowledge is not documented formally and captured at the corporate level.

1.81 In the fall of 2003, the NRC started an HRM environmental analysis. This comprises a review of challenges from the perspectives of worldwide and federal government science and technology, and an assessment of the HRM practices in institutes, programs, and branches. The analysis does not yet include an adequate assessment of risks and opportunities.

1.82 **HRM strategic goals, plan, and priorities are too broad to provide direction.** The NRC's strategic planning guidelines indicate that strategic goals and objectives are to provide the framework for more detailed levels of strategic planning. The framework should clarify the vision and address strategic opportunities and organizational issues.

1.83 In its 2003–04 Report on Plans and Priorities, the NRC defined its HRM strategic goals in generic terms, such as "recruit and retain highly qualified people, reward professional development and productivity, provide an outstanding place to work . . . ." However, these goals, and the related plan and priorities, are so broad that they can include almost any HRM initiative; thus they do not provide direction or establish key priorities. One of the NRC's priorities is to implement a new employment philosophy by 2006. This philosophy is an ideal vision of human resources management and sets forth best practices in all HRM areas. This was not intended to suggest priorities.

By the end of our audit, the NRC was debating its future HRM priorities to make them more strategically focussed.

1.84 **Need to develop an effective partnership.** To successfully develop and implement an HRM strategic plan, the Human Resources Branch needs to be actively involved in the organization's overall strategic planning and management processes. This would ensure that strategic initiatives are evaluated on their human resources implications. It would also allow the Branch to obtain a better understanding of the missions of institutes, programs, and branches and the issues confronting institute managers.

1.85 In May 2003, the NRC modified the role of the Human Resources Management Steering Committee to ensure that it focusses on high-priority human resource issues instead of directing the HRM agenda. This provides the NRC with an opportunity to review the outdated 1993 policy on the Human Resources Branch roles and responsibilities and to build an effective partnership between the Branch and senior management to set the appropriate strategic direction.

1.86 **Recommendation.** The National Research Council should continue its environmental analysis based on credible, factual, and future-oriented information at institutes, programs, and branches. It should focus on the most relevant human resources management challenges as a basis for setting priorities. The National Research Council should also clarify its strategic goals and develop measurable objectives linked to those priorities within a defined period of time. The Human Resources Branch should play a partnership role with senior management in setting the strategic direction.

National Research Council's response. The National Research Council agrees with these recommendations and will continue its efforts to ensure that the current and future human resources (HR) challenges and needs of the institutes, branches, and programs are identified. This environmental analysis will form the basis for establishing human resources management priorities for the organization. This priority-setting process is well underway, with the first comprehensive HR plan scheduled for completion in Spring 2004. The NRC has already taken steps to ensure that HR planning is integrated with and supportive of strategic business planning, including the development of measurable objectives. To emphasize the essential strategic partnership, the Director General of the Human Resources Branch will become a member of the Senior Executive Committee.

The critical challenges identified in the recommendation are consistent with the human resources management priorities outlined in the NRC Report on Plans and Priorities for 2004–05. In this context, the NRC is in the process of building capacity to address recruitment, hiring, succession planning, and compensation issues.

An action plan is needed to implement the strategic direction

1.87 Given the comprehensiveness of the new employment philosophy, the number and diversity of NRC institutes, and the limited resources available, we expected to see an HRM action plan focussed on priorities.

1.88 In the absence of HRM priorities derived from an environmental analysis, the NRC used the Human Resources Management Steering Committee to determine the overall agenda for HRM. The Committee dealt with issues that mainly represented the pressing immediate needs rather than changes needed to meet the NRC's future challenges.

1.89 In our review, we focussed on the HRM issues as identified by the institutes we visited and by some Human Resources Branch representatives. These issues included the NRC's ability to continue recruiting highly qualified researchers, including the impact of compensation for researchers and the need for succession planning.

1.90 **Recruiting and hiring practices need to be more tailored to the NRC's needs.** Managers and researchers expressed concern about the time it takes to hire a new employee through an external competition and the lack of flexibility in attracting highly qualified researchers. The NRC supports the use of networking to identify excellent potential candidates in research areas. Its 2002–03 records show that over one third of its researchers were recruited by "word of mouth." However, the NRC has not yet put in place a specific hiring procedure that responds expeditiously to the operational requirements of its institutes and is consistent with its general staffing objective and policy. It risks losing excellent candidates unless the current hiring process is tailored to the needs of institutes.

1.91 The NRC recently reviewed its recruitment practices and activities to find innovative ways of recruiting staff and linking all activities in a comprehensive manner. It developed a global recruitment strategy that focusses on targeted recruitment activities that emphasize reputation- and image-building. It has also been conducting an extensive review of its hiring practices, with the objective of streamlining the process to be more efficient and effective.

1.92 The NRC has proposed many changes to its current recruiting and hiring practices. In our opinion, these changes should be pilot-tested in some institutes, with a focus on highly qualified researchers, before full implementation.

1.93 The NRC's Vision 2006 goals emphasize recruiting highly qualified people, while its employment philosophy emphasizes looking for the "best of the best." In light of the funding available and the anticipated shortage of researchers, the NRC needs to clarify what type of people it needs to be a leading-edge organization in research. It also needs to align its recruitment, staffing, performance management, and pay policies accordingly.

1.94 **Managers view compensation for researchers as an important challenge.** Many managers and senior researchers we interviewed emphasized the issue of compensation competitiveness with universities and industry in their communities as a road block in attracting highly qualified researchers. Furthermore, the available funding is not always sufficient to cover a full term of employment or limits the capacity of institutes to staff researchers in continuing positions, where appropriate. We therefore expected that the

NRC would have taken steps to closely examine the issue of salary competitiveness for researchers.

1.95 The NRC has no compensation policy. Such a policy is necessary to specify how the NRC will pay its employees and how it positions itself in relation to competitors. The policy should consider internal and external factors that affect the NRC's capacity to deliver its mandate.

1.96 The NRC has not carried out a thorough study to determine whether there are institute- and program-specific issues it should be dealing with related to compensation of researchers. It has no quantitative or qualitative data from managers and researchers to determine the nature and extent of the problem related to the competitiveness of salaries. As well, it has no data on the number of potential candidates for researcher positions who refused to apply in 2001–02 and 2002–03 due to compensation or other considerations. Since networking is one of the key methods for recruiting, project leaders in institutes have information on researchers who were not interested in jobs at the NRC because of compensation or other considerations. In the fall of 2003, the NRC planned to build its capacity to deal with compensation issues.

1.97 **Urgent need for succession planning.** Our review of demographic data compiled annually at the institutes we visited indicates that an average of 28 percent of researchers will be eligible for retirement in five years. We share the concern of the NRC's managers and senior researchers about the researchers' current demographic profile and the fact that universities, an important source of recruitment for the NRC, have the same demographic profile. An academic study estimated that over the next eight years, universities are going to need 10,000 PhDs to replace retiring faculty members, and Canada is going to produce only 4,000 of them. In addition, the NRC has a unique situation with employees, particularly researchers, who stay long beyond normal retirement age at very high wages. The NRC will need to address this issue in conjunction with the need for new expertise in some institutes. These challenges need to be taken into account in the near future.

1.98 **Recommendation.** The National Research Council should develop a comprehensive human resources management (HRM) action plan in line with an HRM strategic plan. The action plan needs to address the critical challenges of recruitment, hiring and compensation practices, and succession planning at both the corporate and institute levels.

National Research Council's response. The National Research Council agrees with these recommendations and will continue its efforts to ensure that the current and future HR challenges and needs of the institutes, branches, and programs are identified. This environmental analysis will form the basis for establishing human resources management (HRM) priorities for the organization. This priority-setting process is well underway, with the first comprehensive HR plan scheduled for completion in Spring 2004. The NRC has already taken steps to ensure that HR planning is integrated with and supportive of strategic business planning, including the development of measurable objectives. To emphasize the essential strategic partnership, the Director General of the Human Resources Branch will become a member of the Senior Executive Committee.

The critical challenges identified in the recommendation are consistent with the HRM priorities outlined in the NRC's Report on Plans and Priorities for 2004–05. In this context, the NRC is in the process of building capacity to address recruitment, hiring, succession planning, and compensation issues.

Performance measurement and reporting

Measuring the performance of research and development activities is complex and difficult

1.99 Research results come in many forms and become evident at different times. For example, sometimes the only identifiable result in the near term is an increase in the body of knowledge. That new knowledge may turn out to be of pivotal importance at some unknown time—possibly years in the future or in another discipline. The complexities of measuring performance at the NRC are magnified by the diversity of its research and development activities, carried out in some 20 institutes and technology centres across Canada as well as in a variety of programs and initiatives.

1.100 The NRC has several years of experience in results measurement, including experience with ongoing measurement and periodic program evaluation. In 1996 it established its first corporate performance framework and, as part of that framework, developed definitions of common performance indicators and performance reporting outlines for its institutes, programs, and branches. In 2003 it launched a new corporate performance management framework for Vision 2006 and was implementing it as we carried out this audit; the framework is scheduled to be completed by 2004–05. At the time of our audit, the NRC was also leading a government-wide project intended to address many of the common challenges to performance management in research organizations. The project, involving about 20 other federal science-based departments and agencies, is expected to develop into an ongoing network for those organizations.

1.101 Although the NRC was in a period of transition for measuring and reporting on its performance, we focussed our audit work in this area on its new performance management framework and its most recent Performance Report.

The new performance measurement framework poses challenges

1.102 In our view, the new performance measurement framework incorporates important and encouraging advances over the one it replaces. The more important of these are the following:

- The NRC plans to use the framework to move from performance measurement to performance management.
- The new framework is more focussed and manageable in its approach to results measurement, with 28 key indicators instead of the more than 80 used previously.

- The information for the indicators will come from a variety of sources, including ongoing data collection, program evaluation studies, bibliometric analyses, and peer reviews.

1.103 However, the NRC has developed few meaningful standards or targets against which to compare results achieved. Measuring results is a necessary but not sufficient step in measuring performance. Measuring performance requires some assessment or analysis of achievements against realistic and meaningful expectations; these are set out, for example, as targets or standards. Only two of the strategic outcomes associated with the five strategic pillars of the NRC's Vision 2006 have concrete targets. However, these are targets only for 2006 and provide no basis for measuring performance in the intervening period.

1.104 Achieving desired results is important, but achieving value for money is also important. One requirement for assessing performance, therefore, is to link results with the costs incurred in achieving them. We found that the NRC's financial information systems compile cost information along three business lines, rather than in relation to the key performance indicators or the five strategic pillars, and the NRC has no plans to change this. We believe that the failure to link results with costs limits the usefulness of the NRC's corporate performance management framework for purposes of management as well as accountability to Parliament.

1.105 In February 2002, an internal audit was conducted to assess the NRC's progress in implementing the recommendations in our 1994 Report, Chapter 10, Science and Technology: Management of Departmental Science and Technology Activities. The audit found there was no uniform automated system or process for institutes to gather performance information for reporting to the corporate level. An October 2002 internal audit to assess the NRC's management of partnerships found errors in the performance information related to collaborative partnerships in four of the five institutes audited. The NRC informed us that while there is little verification of the reliability of performance information, efforts are being made to simplify and automate data gathering, thus easing the burden and reducing the possibility of error. In addition, risk-based verification of performance information is a potential area of future internal work.

1.106 Implementing the performance management framework throughout the NRC is a complex undertaking, extending over a considerable period of time. Although the NRC has identified the planned start and end dates for several major tasks, it does not have a comprehensive, structured implementation plan that sets out such details as responsibilities for completing tasks, the nature of the tasks, the resources that will be required, and the costs that are likely to be incurred.

1.107 Moreover, we noted that there are already signs of some slippage in achieving planned milestones. For example, definitions for the new key performance indicators were to have been developed and communicated across the organization in the summer of 2003. This milestone, which could be significant in assuring the quality of the 2003–04 performance information, was not achieved.

1.108 **Recommendation.** The National Research Council should establish clear and concrete targets for the results measured by its key performance indicators. It should also move urgently to establish a comprehensive and adequately resourced plan for addressing gaps and implementing its new corporate performance management framework. This planning process should include steps to link results to the costs incurred in achieving them and continue to explore ways to strengthen systems and practices for assuring the reliability of performance information.

National Research Council's response. The National Research Council is committed to and will continue to implement and improve its new performance management framework as part of the Modern Comptrollership initiative. Actions are underway to establish a comprehensive and adequately resourced plan to address the gaps in the corporate performance management framework, including setting performance targets for key performance indicators, developing a system to link resources to strategic outcomes, and building an automated performance data gathering system along with procedures to improve the reliability of performance information.

Performance Report needs to be improved

1.109 We compared the NRC's Performance Report for the period ended 31 March 2003 with the corresponding report tabled one year earlier, and we found it to be a better document. The most recent report has a greater focus on performance and results, including a summary table of key results related to commitments made in its 2002–03 Report on Plans and Priorities and a summary of the findings of recently completed evaluations and internal audits. Further, the overall layout of the report is clearer, and it makes better use of charts and tables.

1.110 We also assessed the most recent Performance Report using the model developed by our Office and outlined in our 2002 Report, Chapter 6, A Model for Rating Departmental Performance Reports. The model is generally consistent with the Treasury Board Secretariat's guidelines for performance reporting, released in 2001. It is important to note that we did not audit the information in the Performance Report.

1.111 Although information for the new key performance indicators is not yet available to the NRC, its most recent Performance Report is presented within the context of Vision 2006. We noted some strengths and several ways that it can be improved and provide better accountability to Parliament.

1.112 The report includes a good discussion of the contribution of the NRC's planned results to relevant government priorities. In addition, it demonstrates clearly that planned results are consistent with the NRC's mission and mandate and its operating environment. However, the report does not include a discussion of risks to the achievement of planned results.

1.113 A summary table in the report sets out key results against performance commitments made in the 2002–03 Report on Plans and Priorities. Most of the commitments are to carry out activities or to produce outputs. Only a few are expressed as outcomes (for example, "stimulate foreign investment by creating new technology-based companies and providing highly qualified jobs for Canadians"). For the most part, the commitments do not set out the direction of planned change or concrete targets for the amount of change over a specified time.

1.114 Since most of the performance expectations are not concrete and few of the expected results are expressed as outcomes, it is difficult, if not impossible, for a reader to form any judgment about the NRC's performance or to determine whether the results reported amount to performance successes or shortcomings. Further, the report does not link the resources used by the NRC to the strategic outcomes.

1.115 With few exceptions, information in charts and tables is clearly labelled and easy to understand. However, there are no discussions or representations about the quality of the data.

1.116 Finally, the report does not provide examples of the use of performance information in decision making within the NRC; nor does it provide any discussion of lessons learned or of actions taken or planned to address performance issues.

1.117 **Recommendation.** The National Research Council should present results for its 28 performance indicators against clear and concrete expectations in its future performance reports, and it should link costs to results—at least at the level of strategic outcomes.

National Research Council's response. The National Research Council is committed to continuing to improve its performance report and, by addressing the gaps that exist within its corporate performance management framework, will improve on the comprehensiveness of its reporting to Parliament.

Conclusion

1.118 We found that the National Research Council's corporate governance and accountability structure does not provide an effective challenge of management decisions. We are concerned that the role of the Governing Council is not clear among members of the Council. We are also concerned that the Council is not carrying out the duties we would expect to fulfil the responsibilities assigned to it by the *National Research Council Act*. We noted that the Act has not been updated to reflect best practices in corporate governance as reflected in more recent legislation.

1.119 The National Research Council generally followed good practices for developing its vision, which is closely aligned with the federal government's 1996 science and technology strategy and its 2002 innovation strategy. However, the NRC continues to expand the scope of its research activities and infrastructure, despite a lack of core budget increase. We concluded from our case study of four recent strategic initiatives that there were good consultations with key stakeholders and good analyses of options, risks, and partnership opportunities. However, there was no assessment of the potential financial implications of these initiatives on the NRC's current operations. We also noted the need for a comprehensive assessment of the NRC's research activities.

1.120 We found some examples of good to excellent practices for selecting and terminating leading-edge research projects that are of no immediate commercial interest. However, we also found a number of instances where the NRC did not have the appropriate systems and practices. We identified the absence of priority-setting frameworks and a lack of appropriate project documentation as key areas for improvement to enhance corporate oversight for all projects. This would ensure that all research being performed is providing the best value for Canadians. It is important to note, however, that our findings relate to a sample of projects funded primarily through parliamentary appropriation. They cannot be extrapolated to include projects involving collaborative partnerships, which we did not review.

1.121 The NRC has recognized the importance of human resources management (HRM) to achieving its Vision 2006 by making it one of the five pillars and strategic outcomes. However, the environmental analysis supporting the HRM strategic priorities needs to be stronger, and the strategic direction needs to be developed further. In addition, the NRC lacks a comprehensive human resources management action plan in line with an HRM strategic plan that will enable it to address future critical challenges in the institutes, programs, and branches. We are concerned that the lack of a clearly supported way forward and the NRC's challenges with succession planning could limit its ability to conduct the future research activities of its institutes and programs as planned.

1.122 In developing a new performance management framework, the NRC has taken an important step toward managing for results and improving performance reporting in its Performance Report. However, gaps remain in the framework and the NRC faces challenges in implementing it. Key weaknesses we noted included few meaningful standards or targets against which to compare results achieved, no means to link costs with results, no uniform automated systems or processes for gathering institute performance information, and the absence of a comprehensive and structured plan for implementing the framework.

About the Audit

Objectives

Our audit objectives were

- to assess the National Research Council's (NRC) systems and practices for setting strategic direction for its scientific research activities, including its corporate governance and accountability structure; and
- to determine whether the NRC managed these activities in a way to maximize results and whether it measured and appropriately reported the results and impacts of its efforts.

Our more specific objectives were to determine whether the NRC

- periodically reassesses the appropriateness of its research activities and whether its strategic decisions are made with adequate consideration of risks, options, stakeholders, and potential impacts;
- has appropriate systems and practices for selecting and terminating research projects, and ensuring adequate corporate oversight;
- is able to ensure that it has sufficient qualified staff available for its current and future needs; and
- is able to use performance information on its key activities to effectively monitor and manage its operations and report to Parliament on the achievement of its objectives.

Scope and approach

Our planning work included a review of all the NRC's key activities and programs. This was done from February to June 2003 through site visits to 15 NRC institutes; a review of key documents; numerous interviews of NRC staff (President, vice-presidents, all corporate branch directors general, Director General of the Industrial Research Assistance Program, Director General of the Canada Institute for Scientific and Technical Information, and directors general of institutes visited) and of some key stakeholders (partners in industry, universities, and government).

Based on our knowledge of the NRC and its key challenges, we assessed the significance, risks, auditability, and interest to Parliament of the NRC's activities and programs. We identified four lines of enquiry: setting of corporate strategic direction, research management at the institute level, human resources management (HRM), and performance measurement and reporting.

We selected a sample of recent strategic decisions as a case study to assess the quality and adequacy of information available for decision making and assess the overall decision-making process. We selected eight institutes to assess research project management practices and six institutes to assess HRM practices.

We conducted numerous interviews with NRC Governing Council members, senior executives, and staff. We also examined various NRC documents, including its most recent Performance Report (2002–03) to assess the adequacy of its accountability reporting.

Our audit did not include a review of the quality of the NRC's research. Program evaluations to assess whether program objectives are being met are the responsibility of the NRC. Since 2001, the NRC has conducted five evaluations—the Biotechnology Program (delivered by five NRC institutes), the Institute for Chemical Process and Environmental Technology, the Industrial Research Assistance Program, and two initiatives supported by the NRC (the Tri-University Meson Facility and the Canadian Technology Network).

Criteria

We drew our audit criteria from the NRC's enabling legislation, guidelines, and key documents such as Vision 2006, Report on Plans and Priorities (2003–04), Performance Report (2001–02), and internal audit reports. We also consulted the Treasury Board Secretariat's modern comptrollership practices and the expectations developed by our Office based on our experience in value-for-money auditing and on generally accepted good management practices.

- We had the following expectations:
- The NRC's corporate systems and practices should provide for periodic reassessment of the value and continuing relevance of existing research areas. They should ensure that its strategic decisions and priorities are linked to its mandate and the government's agenda; established after consultation with key stakeholders; based on a thorough analysis of its operating environment, options, risks, and future impacts; and reflected in the allocation of internal funds.
- The NRC should have appropriate systems and practices for selecting, monitoring, and terminating research projects to ensure the best value for Canada. We would expect this to include ensuring risk analysis, peer reviews, identification of potential uses and users, periodic review of projects' value, corporate management oversight, and assurance of a link to the NRC's vision and goals.
- The NRC should have a competent workforce with the appropriate mix of employment relationships (permanent, temporary, contract personnel, or partnerships) to achieve its short- and long-term strategic and operational objectives, in a timely and cost-effective way. We would expect the NRC's systems and practices to include the definition of desired key competencies; strategies to meet the desired workforce profile, and adequate strategies for recruitment, selection, hiring, employment, termination/retirement, and training. These would be aimed at ensuring that staff have the desired attributes and that the NRC has the flexibility to meet operational requirements, has adequate turnover of staff, and has the ability to maintain the overall competency of its workforce.
- The NRC's performance management framework should provide clear and concrete performance expectations and credible and balanced performance results to allow for effective management of its vision and promote good accountability to Parliament and Canadian taxpayers.

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Report of the Auditor General of Canada to the House of Commons—March 2004

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2004

Report of the
Auditor General of Canada
to the House of Commons

MARCH

Chapter 2
Health Canada—
Regulation of Medical Devices

Office of the Auditor General of Canada

The March 2004 Report of the Auditor General of Canada comprises seven chapters, a Message from the Auditor General, and Main Points. The main table of contents is found at the end of this publication.

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Ce document est également disponible en français.

© Minister of Public Works and Government Services Canada 2004
Cat. No. FA1-2004/1-2E
ISBN 0-662-36242-X

Chapter

2

Health Canada

Regulation of Medical Devices

All of the audit work in this chapter was conducted in accordance with the standards for assurance engagements set by the Canadian Institute of Chartered Accountants. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.

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Health Canada
Regulation of Medical Devices

Main Points

2.1 While Health Canada has made progress in important aspects of managing risks related to medical devices before they are made available for sale, it needs to better manage risk after they are available for sale. As a result of the gaps in its Medical Devices Program, Health Canada does not have a comprehensive program to protect the health and safety of Canadians from risks related to medical devices, even though it committed to such a program over a decade ago. Its failure to deliver such a program compromises Health Canada's ability to protect health and safety, which could translate into a growing risk—risk of both injury and liability.

2.2 The current Medical Devices Program manages risks before products are made available for sale, through quality systems requirements and pre-market activities.

2.3 However, to better manage risks after products are available for sale, Health Canada needs to have a more proactive inspection program at the post-market phase to verify that industry is complying with the Medical Devices Regulations, and it needs a better approach to managing risks related to the sale of unlicensed medical devices. An improved post-market surveillance system is also required to provide timely, accurate, and complete information about adverse events once devices are in use. And once safety concerns are identified, there must be better communication in a timely manner with those who need to know.

2.4 Health Canada is taking only limited action to address the risks posed by the reuse of single-use devices. As one of the entities responsible for protecting the health and safety of Canadians, it must take action immediately.

Background and other observations

2.5 Equal and timely access to quality health care is a priority for Canadians. This includes timely access to medical devices, which play an important role in all stages of the delivery of quality health care. Medical devices such as blood test kits, diagnostic imaging equipment, and heart valves are used to diagnose, treat, mitigate, and prevent diseases and medical conditions.

2.6 The Medical Device Review Committee was established in 1991 to formulate recommendations to the Minister of Health concerning the regulation of medical devices and associated activities. A 1992 report of the Committee was used to prepare the Development Plan for an Improved

Medical Devices Regulatory Program. This Plan and the consultation with stakeholders that followed formed the basis of a new Medical Devices Program that began with the introduction of new Medical Devices Regulations in 1998. Since then, Health Canada has introduced some new activities and made improvements to some existing activities, but significant gaps and weaknesses remain.

2.7 Our audit examined how Health Canada manages the risks and benefits related to medical devices at each stage of the product life cycle of a licensed device. Because Health Canada responded to the Medical Devices Review Committee's report and made efforts to implement changes, we used the Department's response as the standard against which we measured the Medical Devices Program. We also examined how the achievements and challenges facing this Program were measured and reported to Parliament.

2.8 Health Canada is aware of the gaps and weaknesses in the Program, but has made limited efforts to address them. Limited financial and human resources and limited progress in advancing international regulatory co-operation prevent Health Canada from addressing these gaps and weaknesses. This in turn, prevents it from delivering the Medical Devices Program as designed.

2.9 Our findings indicate that the current Program is not sustainable. As such, Health Canada must make a choice: It must provide adequate resources to deliver the Program as designed or redesign the Program and the Regulations to allow for health and safety risks to be managed in a way that requires fewer resources.

2.10 Health Canada needs to act to ensure that Canadians have timely access to all available medical devices. It also needs to play a more active role in the conduct of investigational testing.

2.11 Finally, Health Canada needs to improve its evaluation, measurement, and reporting of the results of its Medical Devices Program. This is especially important given the challenges that the Program faces and the questions about continuing with the current Program or redesigning it.

The Department has responded. Health Canada's responses to our recommendations are included in this chapter. The Department has responded positively to our recommendations and has agreed to take corrective action. In some instances, the action is already under way.

Introduction

The importance of medical devices in quality health care

Health care professionals—Professionals who provide health care services, including doctors, surgeons, nurses, dentists, dental assistants, and psychologists.

Therapeutic products—Health products that are used to diagnose or treat illness, including medical devices (such as blood test kits, diagnostic imaging equipment, heart valves), over-the-counter drugs (such as ASA, allergy medication), prescription drugs (such as asthma medication, blood pressure medication), natural health products (such as echinacea, vitamin supplements), biologic and genetic therapies (such as blood, vaccines), and organs and tissues (such as hearts and lungs for transplant).

2.12 Equal and timely access to quality health care is a priority for Canadians. This includes both services provided by health care professionals and therapeutic products such as medical devices. Medical devices play an important role in all stages of the delivery of quality health care. Exhibit 2.1 shows how important medical devices are to health care.

2.13 The manufacture and sale of medical devices are subject to the *Food and Drugs Act* and the Medical Devices Regulations. According to the *Food and Drugs Act*, a medical device is defined as "any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in human beings and animals for:

- the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms,
- restoring, correcting or modifying a body function or the body structure,
- diagnosis of pregnancy, or
- care during pregnancy and at, and after birth of the offspring, including care of the offspring, and includes a contraceptive device but does not include a drug."

Exhibit 2.1 Medical devices are important to health care: The example of a patient with cardiovascular disease

Cardiovascular diseases are a leading cause of hospitalization in Canada. Statistics Canada has estimated a 36 percent increase each decade until 2026 in the number of hospitalizations for heart attack. Projections for caseload at the University of Ottawa Heart Institute are even more dramatic. Between 2003 and 2005, the Institute is projecting a 100 percent increase in defibrillator implants, and a 60 percent increase in pacemaker implants (both class IV medical devices).

A cardiac patient who needs a medical device like a stent or pacemaker may depend on over 400 devices, during non-invasive cardio exams, open heart surgery, and post-operative care. These devices are often highly complex, computerized machines, upon which the survival of a patient may depend.

For diagnosis, devices like a blood pressure monitor, diagnostic imaging equipment such as magnetic resonance imaging (MRI), or a stethoscope, would be used. If a patient needs a stent installed, some of the devices required would include an X-ray machine, an angiograph, catheters, a stent and balloon, and special monitors for temperature and pulse. If a patient needs a pacemaker, the surgery would involve at least 40 devices for anesthesia and between 100 and 200 devices for the surgery. Some examples include a fluoroscope to view the patient's heart and blood vessels, catheters, an array of special instrumentation, a bypass machine, ventilators, vaporizers, oxygenators, and multiple-infusion pumps. After surgery, a new set of devices are introduced for post-operative care.

Source: University of Ottawa Heart Institute

Examples of the four classes of medical devices

Class I—Bandage, toothbrush, hospital bed

Class II—Condom, tampon, surgical gloves, magnetic resonance imaging equipment

Class III—Home glucose test kit, hip replacement implant, ultrasound diagnostic imaging equipment

Class IV—HIV test kit, implantable defibrillator, pacemaker

2.14 The Medical Devices Regulations apply only to devices intended for human use. The Regulations categorize medical devices into four risk classes based on potential to cause harm. Class I represents the lowest-risk; class IV represents the highest-risk. All manufacturers of class I devices who do not sell through a licensed establishment, all importers, and all distributors require an establishment licence to sell their products in Canada. Manufacturers of class II, III, and IV devices require a device licence for each device or grouping of devices to sell their products either to importers and distributors or directly to purchasers in Canada. All establishment and device licences must be renewed annually.

2.15 Canadians consume $5 billion in medical devices annually. Every Canadian who visits a doctor or dentist for an examination, has a diagnostic test, or undergoes surgery will encounter many devices. It is estimated that, in 2001,

- 787,000 Canadians had a non-emergency CT (computed tomography) scan and 647,000 had a non-emergency MRI (magnetic resonance imaging) to assist in diagnosing a health problem;
- 100,000 Ontarians had an emergency CT scan;
- 70,000 Canadians received a heart valve or stent, and 10,000 received a pacemaker;
- 250,000 Canadians had the lens of an eye replaced with an intraocular lens; and
- 50,000 Canadians had an artificial joint implanted in a hip, knee, shoulder, or elbow.

2.16 Medical devices are largely based on technology. As advances are made in technology, the number of devices and their complexity will increase. For these reasons, it is expected that the medical devices industry will continue to grow in the future, both in size and in importance.

Stakeholders in medical devices

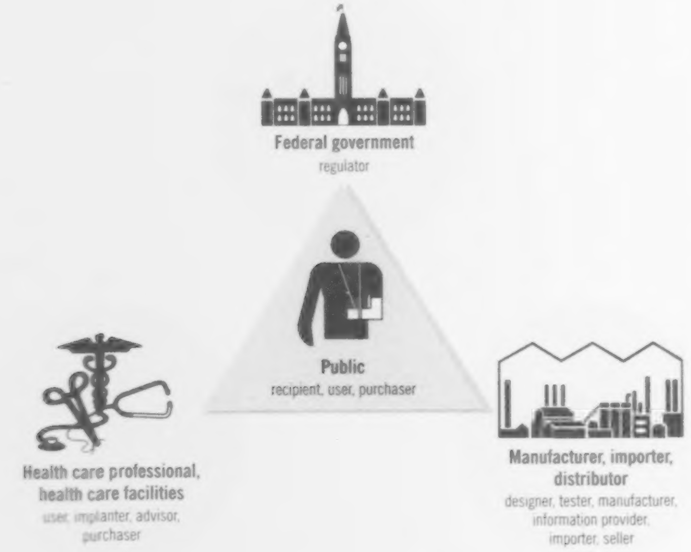
Health care facilities—Places where health care is provided, such as hospitals, clinics, nursing homes, and doctors' and dentists' offices.

2.17 There are four main stakeholders in medical devices. Exhibit 2.2 shows how their relationship is interdependent. The primary stakeholder is the public. Health care professionals and the health care facilities for which they work play an important role in the safety of devices. The medical devices industry—including manufacturers, importers, and distributors—and the federal government are also important in helping to ensure the safety of devices.

2.18 The public uses medical devices to receive some health benefit. However, with this benefit comes some level of potential risk since the quality and safety of devices can never be absolutely guaranteed.

2.19 The public has limited control over the risks and benefits to which they are exposed. Ultimately, they must trust others, such as health care professionals and manufacturers of therapeutic products, to provide safe and effective services and products. It is this need to trust manufacturers that defines the responsibilities of the federal government: to help protect the public from undue health and safety risks that are posed by therapeutic products and are beyond their influence.

Exhibit 2.2 The four main stakeholders in medical devices


Federal government
regulator
Public
recipient, user, purchaser
Health care professional, health care facilities
user, implanter, advisor, purchaser
Manufacturer, importer, distributor
designer, tester, manufacturer, information provider, importer, seller

2.20 Health care professionals play a critical role in relation to medical devices. To provide the public with information on the risks and benefits of a device and to learn how to use or install a device, the health care professional must rely on the manufacturer. And much like the public, health care professionals rely on government to help ensure the safety and therapeutic effectiveness of products.

Therapeutic effectiveness of products—The effectiveness of a product to identify, eliminate, or reduce the effect of an illness.

2.21 Health care professionals also play a significant role in helping to ensure the continued safety of medical devices for the public. They are often the first to become aware of an adverse event related to a device; this makes them the most important source of information on adverse events. When this information comes to their attention, they have a professional responsibility to pass it on to the manufacturer and/or the federal government. By doing so on a timely basis, they assist the federal government in assessing and communicating a safety concern so that future problems can be prevented.

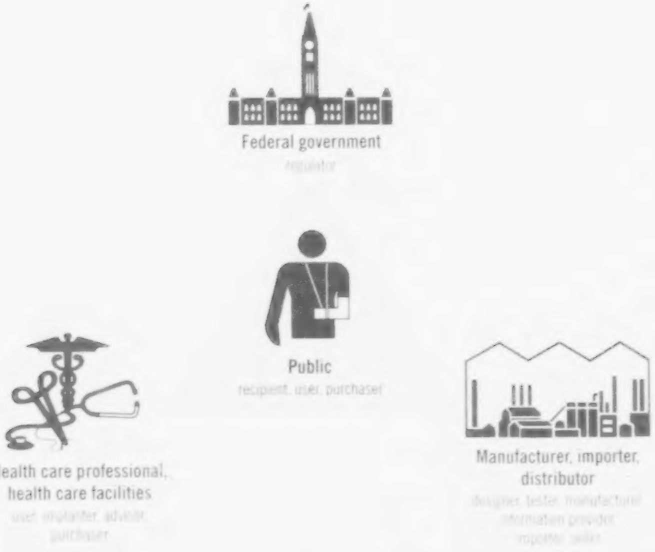
Adverse event—An incident that has led or could lead to patient or user injury. It can be caused by failure of the device or improper use due either to human error or to inadequate labelling or directions.

Safety concern—A problem with a device that suggests that continued use could result in harm to the patient and consumer.

2.22 The legal responsibilities of the medical devices industry are clearly outlined in the Medical Devices Regulations. Consistent with the federal government's current approach to regulation, which involves increased reliance on industry, these Regulations place significant responsibility on the industry to do all it can to protect the health and safety of the public. Although the specific requirements in the Regulations vary among the four classes of devices and among manufacturers, importers, and distributors, in general the Regulations require that the industry

- be certified to operate a system that helps ensure quality in the design and manufacture process and that is in accordance with standards set by

Exhibit 2.2 The four main stakeholders in medical devices


Federal government
regulator
Public
recipient, user, purchaser
Health care professional, health care facilities
user, implanter, adviser, purchaser
Manufacturer, importer, distributor
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- be certified to operate a system that helps ensure quality in the design and manufacture process and that is in accordance with standards set by the International Organization for Standardization (ISO) (class II, III, IV);

- obtain authorization from Health Canada to conduct investigational tests (class II, III, IV);
- possess evidence that a medical device meets the requirements for safety and therapeutic effectiveness to obtain authorization to sell that medical device in Canada (all classes) and provide this evidence to Health Canada for its evaluation before licensing (class III and IV);
- hold an establishment licence if they are an importer or distributor of medical devices (all classes) or a manufacturer of class I devices who do not sell them through a licensed establishment (class I);
- maintain records of all reports of adverse events and complaints received and the actions taken on these reports and complaints (all classes);
- report all serious adverse events to Health Canada (all classes); and
- maintain records of distribution for all devices (all classes) and a registration system for certain implantable devices (certain class IV devices).

2.23 The federal government, as federal regulator, has a legislated responsibility that is outlined in the *Food and Drugs Act* to protect the health and safety of Canadians. In delivering on these responsibilities, the federal government helps ensure that the public has timely access to all available safe and effective devices; it also helps ensure the continued protection of the public by informing those who need to know of any safety concerns on a timely basis.

2.24 As previously noted, the safety of a medical device can never be absolutely guaranteed. Given this, the role of the federal government is to assess the benefits derived from the use of a device against the associated risks. Based on this assessment, the federal government decides whether the health and safety of Canadians would be compromised by using the device.

2.25 In recent years, courts have held that in some circumstances public authorities could be found to owe a duty of care to certain persons. In cases where a public authority did not exercise diligence, the public authority has been found negligent and liable to those injured by that negligence. Health Canada is defending a number of court challenges where it is alleged that the Department breached a duty of care it owed to a group of persons injured by medical devices. Specifically, Health Canada is defending class action lawsuits related to breast implants and jaw implants. This potential liability reflects an important aspect of the use of medical devices—that the public rely on the federal government to help protect them from health and safety risks that are beyond their influence.

2.26 As one of the four main stakeholders involved in medical devices, Health Canada is being called upon more and more to explain to the courts its role as the regulator of medical devices and to defend against allegations that it is responsible for damages suffered by Canadians who claim to have been injured by a medical device. In other words, because it is one of the four main stakeholders, Health Canada is sued along with other stakeholders in what are typically product-liability and medical-malpractice lawsuits.

Health Canada's Medical Devices Program

2.27 Health Canada is responsible for delivering programs to protect the health and safety of Canadians in relation to all therapeutic products, including medical devices. The Department's Health Products and Food Branch is responsible for the Medical Devices Program. This Program is delivered jointly by the Medical Devices Bureau, the Health Products and Food Inspectorate, and the Marketed Health Products Directorate. The authority for this Program comes from the *Food and Drugs Act* and the Medical Devices Regulations.

The intracardiac navigation system allows the surgeon to locate the intracardiac catheter inside a patient's heart.

Source: Medtronic of Canada Ltd.

2.28 A report issued by the Medical Devices Review Committee in 1992 guided the development of the current Medical Devices Program. This Committee was established to formulate recommendations to the Minister of Health concerning the regulation of medical devices and associated activities. Our audit examined how Health Canada implemented its new Medical Devices Program as compared to Health Canada's response to the Committee's report.

2.29 The goal of the Medical Devices Program is to ensure that medical devices available in Canada are safe, effective, and of high quality. This is done through a regulatory framework, whereby the level of effort given to a device is dependent upon the risk class of the device and whereby the safety and effectiveness of medical devices are assessed through a balance of quality-systems requirements, pre-market activities, and post-market activities.

2.30 In 2002 over 100 licences for new class IV devices, almost 550 licences for new class III devices, and almost 1,500 licences for new class II devices were issued in Canada. If a device is changed, Health Canada must authorize the changes. In 2002 Health Canada authorized amendments to 650 licences for class IV, 1,950 for class III, and 3,700 for class II devices. It recently reported that over 40,000 class IV devices, over 175,000 class III devices, and over 240,000 class II devices are currently licensed for sale in Canada. Health Canada has also issued close to 1,300 establishment licences to manufacturers of class I devices, importers, and distributors.

2.31 The budget for the direct costs associated with the Medical Devices Program was $7.4 million in 2002. The Program employed 95.5 full-time equivalent staff in 2002.

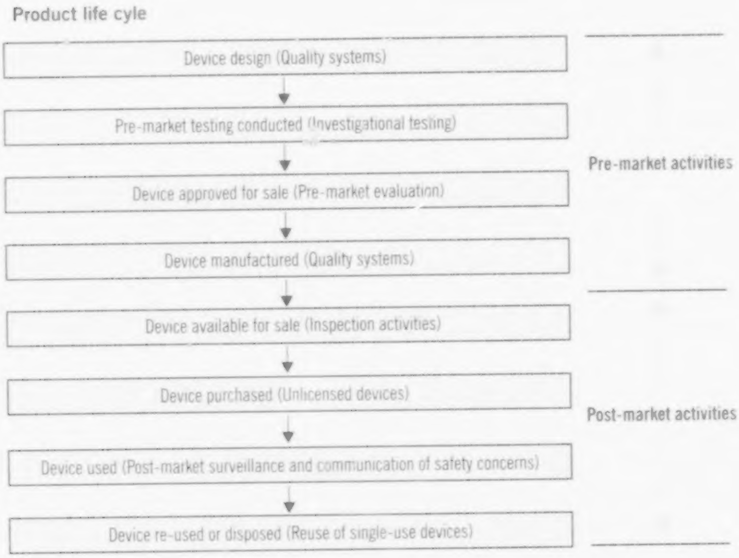
Focus of the audit

2.32 The focus of this audit was Health Canada's Medical Devices Program managed by the Health Products and Food Branch, and in particular the Program activities directed at class II, III, and IV devices. Our objectives were to determine whether Health Canada adequately manages the risks and benefits related to safety and therapeutic effectiveness of medical devices available in Canada, identifies weaknesses in the Program and takes action to address them, and measures and reports the results achieved by the Medical Devices Program.

2.33 We reviewed the 1992 report issued by the Medical Devices Review Committee and the Development Plan for an Improved Medical Devices Regulatory Program prepared by Health Canada in response to that report. We also reviewed documents from the consultations with stakeholders that took place prior to the introduction of the new Regulations. We examined the activities Health Canada engages in to discharge its responsibilities. We made comparisons with the medical devices programs in the U.S. and the UK and with the Drug Program delivered by Health Canada. Finally, we considered the impact of the Medical Devices Program's human and financial resources on Health Canada's ability to adequately discharge its responsibilities.

2.34 Our audit observations follow the product life cycle of licensed medical devices (Exhibit 2.3).

Exhibit 2.3 Product life cycle of a licensed medical device


Product life cyle
Device design (Quality systems)
Pre-market testing conducted (Investigational testing)
Device approved for sale (Pre-market evaluation)
Device manufactured (Quality systems)
Pre-market activities
Device available for sale (Inspection activities)
Device purchased (Unlicensed devices)
Device used (Post-market surveillance and communication of safety concerns)
Device re-used or disposed (Reuse of single-use devices)
Post-market activities

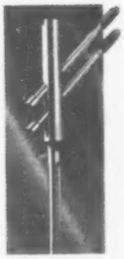
Source: Health Canada

2.35 More information about the audit's objectives, scope and approach, and criteria can be found in **About the Audit** at the end of the chapter.

Observations and Recommendations

The Medical Devices Review Committee

2.36 The report issued by the Medical Devices Review Committee in 1992 contained many observations and recommendations. When these observations and recommendations are taken together, they provide a vision for a comprehensive medical devices program.



The interlocking nail medical device is used to repair fractures in long bones.

Source: Smith and Nephew Inc.

2.37 That vision was for a program that had a number of key attributes and activities (Exhibit 2.4). It was suggested that the Program include regulations that placed significant responsibility on industry and, to a lesser degree, on health care professionals. The Committee recognized the importance of pre-market activities to help ensure the safety and therapeutic effectiveness of medical devices before the products are made available for sale to Canadians. It also recognized that the responsibility for the safety and therapeutic effectiveness of medical devices does not end once the devices are on the market; this acknowledges that post-market activities are critical to an effective regulatory program.

2.38 Because the medical devices industry operates in a global economy, the Committee suggested that this Program include active participation in activities related to international regulatory co-operation.

2.39 The Medical Devices Review Committee stressed the importance of providing adequate resources to deliver the Program. It recommended an increase in the resources allocated to the Program and suggested introducing fees to recover part of the cost of the Program; the revenue from this would be used to improve the Medical Devices Program.

Health Canada's response to the Medical Devices Review Committee's report

2.40 Health Canada responded to the report and, with additional help from the Committee, prepared a Development Plan for an Improved Medical Devices Regulatory Program, which proposed changes to its Medical Devices Program. It also engaged in consultations with stakeholders about the proposed changes to the Program. In its 1994–95 Part III Estimates, it informed parliamentarians about the Development Plan and some of the changes that were being introduced based on the Plan. Because Health Canada responded to the report and made efforts to implement changes, we used the Department's response as the standard against which we measured the Medical Devices Program. The Department accepted our use of this standard.

2.41 The first significant change resulting from these efforts was the introduction of the new Medical Devices Regulations in 1998. In addition, Health Canada introduced some new activities and made improvements to some existing activities. These changes addressed some of the concerns contained in the report. In particular, it introduced

- a requirement for a quality system for manufacturers based on the standards of the ISO (International Organization for Standardization);

- establishment licensing of manufacturers of class I devices who do not sell through licensed establishments, importers, and distributors;
- a pre-market notification and licensing system for class II, III, and IV devices that is based on the risk class of the device;
- a mandatory system for problem reporting for manufacturers and importers; and
- cost recovery.

Exhibit 2.4 The Medical Devices Review Committee's report provided a vision for a comprehensive medical devices program

Key attributes

The Medical Devices Review Committee provided a vision for a comprehensive medical devices regulatory program with the following attributes:

- protects the patient and consumer,
- recognizes the responsibilities of industry, health care professionals and facilities, and the federal government,
- supports international regulatory co-operation,
- balances pre-market and post-market activities,
- is open, transparent, and cost effective, and
- incorporates the principles of risk and benefit management.

The Committee recommended that the program do the following:

Pre-market activities

- develop a requirement for a system to help ensure quality in the manufacturing of medical devices,
- develop a policy on managing the risks related to investigational testing,
- using a risk-based approach, evaluate a manufacturer's evidence of the safety and therapeutic effectiveness of a device before it is introduced on the market,
- issue a licence if the evaluation is favourable and renew the licence annually, and
- manage the evaluation process to prevent a backlog.

Post-market activities

- develop an active inspection program to help ensure industry is in compliance with the regulations and to publicly identify those that are not.
- develop a pro-active post-market surveillance system that provides sufficient adverse-events information to allow safety concerns to be identified. Suggestions include, but are not limited to, mandatory reporting of adverse events by manufacturers and health care professionals and ongoing surveillance processes, such as device registries.
- develop a communication plan and methods to disseminate information on health risks and benefits and safety concerns to health care professionals, and the public on a timely basis.
- amend the current legislation to provide additional enforcement options.
- promote education and training for health care professionals on devices.

Source: The Report of the Medical Devices Review Committee, 1992

2.42 However, several significant concerns have not been addressed, which include

- limited progress in advancing international regulatory co-operation;
- limited inspection activity at the post-market phase and no public communication when industry does not comply;
- limited progress in improving the voluntary reporting system for adverse events;
- no risk communication strategy related to medical devices and limited improvement in the communication of safety concerns; and
- cost recovery that was revenue-neutral and therefore did not provide additional funds to support improvements to the Program.

These issues are discussed in greater detail in the following sections of the chapter.

Pre-market activities

Quality systems are a regulatory requirement

2.43 It is recognized by medical devices stakeholders that many serious problems associated with devices are caused by poor design or manufacturing controls. It is also recognized that incorporating quality systems—that is, quality control and quality assurance—into the design and manufacturing processes is a good way to manage these problems (Exhibit 2.5).

2.44 For these reasons, the Medical Devices Review Committee recommended that Health Canada introduce a requirement for quality systems in manufacturing based on international standards.

Exhibit 2.5 Using a quality system prevents problems in the design and manufacturing processes

The purpose of a quality system (quality control and quality assurance) is to prevent and control quality problems in the design and manufacturing processes.

The quality control aspect requires manufacturers to evaluate their processes to identify those activities that are critical to ensuring quality in their products. They then build in controls to help ensure that these activities function consistently to ensure quality during design and manufacture, thereby ensuring consistency in its quality. Examples of critical activities include:

- use of trained employees,
- regular calibration of equipment, and
- confirmation of specifications.

Once all critical activities and controls are identified, the quality system is designed, documented, and incorporated into the processes.

The quality assurance aspect requires the manufacturer to develop procedures for monitoring the controls to help ensure they are working effectively. Monitoring could involve:

- hourly tests of the control (for example, testing equipment calibration),
- daily observation of the control (for example, observing adjustment of equipment), and
- periodic audit of the control (for example, reviewing employee training records).

2.45 We found that Health Canada incorporated a requirement for quality systems in the 1998 Medical Devices Regulations. The Regulations require manufacturers to incorporate quality systems (based on internationally accepted standards for quality systems) into the design process for class III and IV devices. They also require manufacturers to incorporate them into the manufacturing process for class II, III, and IV devices.

2.46 We also found that to help ensure compliance with these regulatory requirements, Health Canada developed a third-party registration system. Health Canada, through the Standards Council of Canada, accredits international audit organizations to carry out certification audits of quality systems on its behalf. Each manufacturer must demonstrate to this accredited third-party registrar that it operates a quality system that complies with the international standards. Once this has been demonstrated, the registrar will issue a certificate, which the manufacturer must submit to Health Canada as part of the application for a device licence or for its annual renewal. Without this certificate, the device will not be licensed for sale in Canada. Certification must be renewed through re-certification audits every three years. Also annual surveillance audits are conducted to ensure that the manufacturer is continuing to respect the quality-system requirements. Finally, registrars must notify Health Canada within 15 days of any certifications that are suspended or not renewed.

Investigational tests are not adequately monitored

2.47 Investigational testing, sometimes called clinical trials, determines the safety and therapeutic effectiveness of a medical device through controlled testing on human subjects. An investigational test is generally designed to

- verify that under specified conditions of use the device performs as intended by the manufacturer, and
- identify any adverse events under normal conditions of use to allow assessment of whether these events are acceptable when assessed against the intended benefits of the device.

2.48 Conduct of investigational tests is important because failure to conduct them safely could result in harm to participants, and failure to conduct effective tests could result in inaccurate results about the safety and therapeutic effectiveness of medical devices. Further, this information plays an important part in Health Canada's decision whether or not to authorize the sale of devices.

2.49 The Medical Devices Review Committee recognized that how investigational tests are conducted is important. Because it observed some confusion by the industry about some of the ethical and operational considerations in investigational tests, it recommended developing a policy to clarify the rules for high-risk devices. However, the Committee did not make direct recommendations about how to manage the risks related to investigational tests. We expected that Health Canada's approach to managing these risks would be consistent with the approach it is taking for other therapeutic products and/or the approaches taken by other international jurisdictions in their medical devices programs.

2.50 We found that the Medical Devices Regulations require manufacturers to seek authorization to use medical devices in conducting an investigational test before the test can begin and to report any serious adverse events that are identified during the test. Before authorization is given, Health Canada reviews, among other things, the test protocol and the credentials of investigators. This review provides Health Canada with information about how the manufacturer intends to conduct the investigational test. Finally, if Health Canada becomes aware of concerns, it can revoke the authorization that allows the device to be used in the test.

2.51 However, we observed that once an investigational test begins, Health Canada does not monitor its conduct through, for example, inspection of the test. More specifically, we found that Health Canada does not

- regulate the conduct of investigational tests as a means to hold manufacturers accountable for the conduct of their investigational tests,
- inspect the tests to help ensure safe conduct in order to protect subjects in the test, or
- inspect the tests to help ensure effective conduct in order to verify the quality or integrity of the results of the investigational test.

Nor does Health Canada verify the quality or integrity of the results of the investigational tests when making its decision on whether or not to authorize the sale of devices.

2.52 Also of concern is that Health Canada has not assessed the adequacy of its approach to investigational testing or the risks associated with its decision not to monitor the conduct of tests. We found that Health Canada's approach to testing medical devices is different from its approach to clinical trials for drugs and also to the U.S. Food and Drug Administration's approach to clinical trials for medical devices. Because of recognized risks related to the safe and effective conduct of clinical trials, drug manufacturers in Canada and medical device manufacturers in the U.S. are required by regulation to follow Good Clinical Practices. In addition, both governments conduct inspections of the clinical trials. It is important that Health Canada consider the appropriateness of these approaches as a means to manage risks related to investigational testing of medical devices.

Good Clinical Practices—An international standard for clinical trials for drugs, which ensures that the data and reported results are credible and accurate and the rights, integrity, and privacy of clinical trial subjects are protected.

2.53 **Recommendation.** Health Canada should assess the risks related to the conduct of investigational tests for medical devices. Based on this assessment, it should take appropriate action to manage these risks.

Department's response. Agreed. Health Canada will assess the current regulatory requirements for the conduct of investigational testing for medical devices, in consultation with those who share in this responsibility, and will take action to manage any risks that are determined not to be fully addressed by the current regulatory framework. Health Canada will initiate consultations by Fall 2004 with the goal to complete these by Summer 2005.

Pre-market evaluation process is consistently followed

2.54 Consistent with the recommendations contained in the Medical Devices Review Committee's report, the Medical Devices Regulations require that all class II, III, and IV medical devices be licensed for sale by Health Canada. Before giving a licence, Health Canada evaluates information provided by manufacturers supporting their claim that the device meets the requirements of the Regulations. The nature of the information required from manufacturers and evaluated by Health Canada and the level of scrutiny of that information by Health Canada depend on the risk class of the device. For example, more extensive information is required for a heart valve than for surgical gloves, and the level of scrutiny of that information is more extensive. That evaluation helps ensure that the health and safety of Canadians will not be unduly compromised by a medical device.

2.55 As previously mentioned, in Canada medical devices are classified into one of four risk classes based on their potential to cause harm, with class I representing the lowest risk and class IV the highest. Factors considered in classifying risk include

- how long the product is expected to be inside the patient (for example, one hour or 10 years);
- how invasive the product is into the body (for example, inserted temporarily or implanted fully); and
- how the device interacts with the patient (for example, a device that does not interact or one that delivers energy to the patient).

To help ensure proper classification, the Regulations provide specific rules for assigning risk class, which are supported by guidelines for both evaluators and manufacturers.

2.56 Class II, III, and IV devices require a licence for each device or grouping of devices. A licence is issued only once Health Canada is satisfied that the device was designed and manufactured under a quality system and meets the safety and therapeutic effectiveness requirements (that is, that the risks have been identified and minimized and the device performs as intended).

2.57 The authorization of a licence for class II devices is largely administrative. The manufacturer must submit an attestation that the device meets the requirements, which is reviewed by Health Canada.

2.58 The authorization of a licence for class III and IV devices is much more involved. Manufacturers must submit evidence, such as investigational test results or laboratory test results, to demonstrate that they meet the requirements of the Regulations. This evidence is then evaluated by Health Canada before a licence is issued.

2.59 If a Class III or IV device meets certain criteria—for example, if there is an emergency need for the device or it is a critical new device—Health Canada offers mechanisms to expedite access to the device. Both the Special Access Program and priority review will result in more immediate attention for those devices that are urgently needed so that licensing is not a barrier to access.

2.60 **Evaluation process.** We found that Health Canada has a structured approach to evaluating the safety and therapeutic effectiveness of medical devices to be sold in Canada. The basis of the approach is the Regulations, which ensure that the level of scrutiny for devices increases with the risk class. It includes standard operating procedures and templates, which provide structure to the evaluators to help ensure consistency in their risk-based decisions on safety and therapeutic effectiveness.

2.61 We examined the evaluation process for a random sample of 10 class II, III, and IV medical devices processed during 2001 and 2002 and 21 appeals and refusals (representing all completed appeals and refusals for 2002). We found that the process was consistently followed. Our review revealed that

- devices that represent the highest risk were subject to the highest level of review,
- reasons for decisions were documented,
- standards were referenced and applied, and
- expertise and experience were incorporated into the review process.

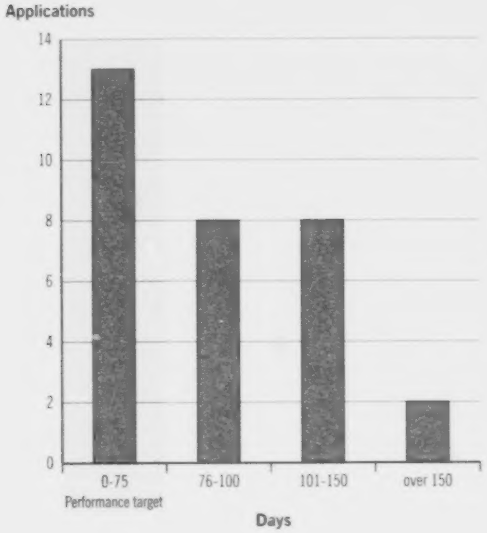
2.62 **Delays in authorizing licences.** While it is important that Health Canada take the necessary time to properly evaluate a device for safety and therapeutic effectiveness, delays in authorizing licences deny Canadians timely access to devices.

2.63 Health Canada negotiated performance targets with the Canadian medical devices industry for authorizing licences within 75 days for class III devices and 90 days for class IV devices. Health Canada also determined that to meet these performance targets for class III and IV devices, it would require the full-time equivalent of 56 employees.

2.64 We found, with a few exceptions, that Health Canada has consistently failed to meet its performance target for class III and IV devices. Since 2000, the quarterly average performance for new applications has ranged from 73 to 113 days for class III devices and 106 to 204 days for class IV devices. The average performance can fluctuate considerably because the number of applications received each quarter can be quite variable. We also found that Health Canada currently has the full-time equivalent of only 36.4 employees assigned to this task.

2.65 To examine this issue more closely, we reviewed the authorization time—that is, the length of time it took to issue a licence after the application was received—for a random sample of 31 class III applications and 29 class IV applications processed during 2002. Because the time spent waiting for additional information from manufacturers is beyond the control of Health Canada, we excluded this time from our calculations. We calculated that for class III files, 42 percent were completed within the target of 75 days and 58 percent required between 76 and 215 days for authorization. The average number of days for authorization was 90; this is 15 days longer than the performance target. For the class IV files reviewed, we calculated that 31 percent were completed within 90 days and 69 percent required between 91 and 361 days for authorization. The average number of days for authorization was 140; this is 50 days longer than the performance target (exhibits 2.6 and 2.7).

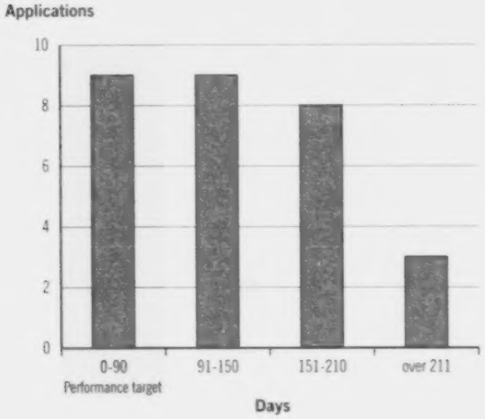
Exhibit 2.6 Total time for authorizing licences for 31 class III applications, 2002



42 percent of applications were processed within the target of 75 days.

58 percent were processed between 76 and 215 days.

Exhibit 2.7 Total time for authorizing licences for 29 class IV applications, 2002



31 percent of applications were processed within the target of 90 days.

69 percent were processed between 91 and 361 days.

2.66 The two main stages in the authorization process are:

- screening—the time for administrative processing and review of the application for completeness upon receipt of the application; and
- review—the time taken to review the application in order to evaluate the safety and therapeutic effectiveness of the device.

There are two reasons why an application may be waiting for review:

- additional information—the time waiting for a manufacturer to provide missing or more complete information; and
- queue—the time that a file is sitting waiting for action.

Each of these influences the length of time it takes for an application to get from receipt of the application to issuance of a licence.

2.67 To better understand the authorization process, we calculated the amount of time that these files spent at each stage in the process. We excluded the time spent waiting for additional information. Our calculations showed the following:

- screening—in 66 percent of the cases, screening was completed within 15 days; only 7 percent were in screening for more than 30 days.
- review—in 77 percent of the cases, review was completed within 10 days; only 5 percent were in review for more than 30 days.
- queue—in 66 percent of the cases, the application was sitting in the queue for 60 days or more; in 23 percent, the application was sitting in the queue for over 120 days (or four months).

2.68 This analysis reveals that since the review of an application takes generally less than 10 days, the review itself does not contribute greatly to the delay. Further, we can conclude that much of the delay in issuing licences within the performance targets is due to files sitting in the queue. While there may be several reasons why Health Canada is experiencing delays, the fact that it is operating with a shortage of 19.6 full-time equivalents or 35 percent of the staff needed is most certainly contributing to these delays.

2.69 Every day that a device is waiting for review, it is not available to Canadians and thus access to that device on a timely basis is compromised. In 2002, Health Canada received 5,000 requests through the Special Access Program, a 683 percent increase in the last four years. Since the staff who process requests through the Special Access Program are the same as those who conduct pre-market evaluations, time spent dealing with these requests is time taken away from working on pre-market evaluations. In order to ensure timely access to devices, Health Canada must deal with the delays in authorizing medical devices.

2.70 **International regulatory co-operation.** International regulatory co-operation involves the co-operation of international regulators in activities such as developing and adopting international standards, harmonizing regulations, conducting joint evaluations, and using mutual-recognition agreements. The Medical Devices Review Committee recognized the advantages of international regulatory co-operation, namely, efficiencies in the program could be gained, requiring fewer resources to carry out the program; and the regulatory burden on manufacturers could be reduced, resulting in more timely access to a greater number of devices.

2.71 In the Regulatory Impact Analysis Statement that accompanied the 1998 Medical Devices Regulations, Health Canada committed to harmonizing regulations with other jurisdictions and using mutual-recognition agreements to allow devices to be evaluated in one jurisdiction and placed on the market in all other jurisdictions without further evaluation.

2.72 We found that while Health Canada has developed an international strategy, limited progress has been made in advancing this strategy. Work on harmonizing regulations is progressing slowly. Canada has three mutual-recognition agreements, with the European Union, Switzerland, and the European Free Trade Association; however, none of these have been operationalized. In addition, Health Canada is not formally using the evaluations of devices completed by other jurisdictions.

2.73 Health Canada has faced a number of challenges in implementing its international strategy. These include the following.

- It can be difficult to get consensus among all players because each jurisdiction defines risk differently, has its own priorities for managing risk, and uses different approaches and standards for managing those risks.
- It can be difficult to exercise international influence because Canada is a small market.
- There is only limited guidance from the Canadian government on which models of international regulatory co-operation are the most efficient and effective and the most socially acceptable to Canadians.

2.74 Because of the advantages of international regulatory co-operation, such as increased efficiency of the Medical Devices Program and reduced regulatory burden, it is important that Health Canada follow through on its international strategy. To manage the challenges of international regulatory co-operation, it is important that Health Canada prioritize its activities. It can continue with those activities that are high priorities and establish international relationships that allow it to benefit from the efforts of other jurisdictions for those activities that are lower priorities.

2.75 **Recommendation**. Health Canada should ensure that Canadians have timely access to all available safe and effective devices. More specifically, it should ensure that all devices are approved within the performance targets and should consider engaging in activities that would allow it to benefit from international regulatory co-operation.

Department's response. Agreed. Health Canada agrees that timely access to devices for Canadians is important and strives to achieve this, with due regard for the potential risk posed to the user and the time and expertise required to evaluate their safety and effectiveness. Health Canada is undertaking a review of current performance targets and processes, particularly in light of the increasingly complex technologies, and corresponding financial resources to determine the reason(s) for not meeting performance targets, and it will implement corrective action. Health Canada's goal for completion of this review and initiation of corrective action is Spring 2005.

Health Canada will build on its history of strong international co-operation by continuing to explore opportunities to work with international regulatory partners to enhance performance. This includes opportunities to harmonize regulatory approaches and utilization of mutual-recognition agreements.

Post-market activities

Inspection strategy needs to be implemented

2.76 Inspection activities involve visiting manufacturers, importers, and distributors to inspect their operations in order to verify that they are complying with the *Food and Drugs Act* and the Medical Devices Regulations. For example, Health Canada may inspect the distribution records of a manufacturer, importer, or distributor to ensure that the records respect the Regulations. It may also review the action taken by a manufacturer, importer, or distributor in response to an adverse event to ensure that the action taken respects the Regulations. Because the Medical Devices Regulations place significant responsibility for protecting the health of Canadians on the industry itself, it is particularly important that Health Canada assess their activities.

2.77 The Medical Devices Review Committee recommended that Health Canada develop an active inspection program with public notification when industry does not comply.

2.78 Health Canada's approach to verifying compliance with the Regulations focusses on three phases in the product life cycle of licensed medical devices: before the product is available at the investigational testing phase; at the manufacturing phase; and after the product is available at the post-market phase. Our observations on inspection at the investigational testing phase are discussed in paragraphs 2.47 to 2.52 and on certification audits (similar to inspections) at the manufacturing phase in paragraphs 2.43 to 2.46.

2.79 Health Canada has an inspection strategy that identifies the importance of inspection activities. However, we found that Health Canada does not engage in any inspection activity at the post-market phase and does not know the extent to which the Regulations are being respected. More specifically, we found that Health Canada does not know the extent to which manufacturers, importers, and distributors are

- operating surveillance systems that are adequate to allow them to identify adverse events after the product is on the market;
- taking appropriate action in response to adverse events or complaints that come to their attention;

- reporting to Health Canada all serious adverse events that come to their attention;
- maintaining adequate distribution records to ensure successful recalls; and
- selling only licensed devices.

Unlicensed devices need to be better managed

2.80 According to the *Food and Drugs Act* and the Medical Devices Regulations, it is illegal to sell a class II, III, or IV device if it does not have a licence. However, we found some evidence that unlicensed medical devices are being offered for sale in Canada. We also found some evidence that it can be difficult to determine whether or not a device is licensed. Because there is no mark on the device or package to indicate whether or not a device is licensed, purchasers must find other means to verify the licence. Because unlicensed devices have not been evaluated by Health Canada for safety and therapeutic effectiveness, there is an increased risk of harm when they are used.

2.81 In general, we found that Health Canada takes action against an unlicensed device only when it is brought to Health Canada's attention, for example, as a result of an adverse event or a complaint. We observed that often its response is to contact the seller to advise him or her to stop selling the product and, when appropriate, to advise him or her to issue a recall until a licence to sell the device is obtained from Health Canada. Both health care professionals and the medical devices industry itself are critical of Health Canada's approach to unlicensed devices. The medical devices industry is frustrated, as it believes that non-compliant sellers are not penalized in any significant way for selling unlicensed devices and therefore are not discouraged from continuing to sell unlicensed devices. Both health care professionals and the medical devices industry would like to see Health Canada take more severe action against those who sell unlicensed devices. Health care professionals are also frustrated because the onus falls on them to verify that a device is licensed—something that can be difficult to do. They believe Health Canada should help ensure that it is easy to verify that a medical device is licensed.

2.82 In cases where Health Canada does prosecute the seller of an unlicensed device, the courts can impose fines of up to $5,000 (the maximum under the *Food and Drugs Act*) or imprisonment.

2.83 Health Canada and other international regulators have identified a number of possible options to help better manage the risks related to unlicensed devices. To help reduce the risk that a purchaser will buy unlicensed devices, these options include continuing to provide education to manufacturers and purchasers, using visual logos or bar code identifiers on licensed devices, or offering a whistle-blowing hotline. In November 2003, Health Canada developed a more user-friendly, searchable Web site to assist purchasers in verifying the status of licences for medical devices. To better deal with identified unlicensed devices, options include amending the

Regulations and the legislation to allow for the issuing of fines or tickets by Health Canada and to allow for larger penalties to be imposed by the courts.

Post-market surveillance activities need to be improved

2.84 Post-market surveillance involves collecting, analyzing, and interpreting information about adverse events. The information is gathered through ongoing monitoring of medical devices for concerns about safety and therapeutic effectiveness once they are available for sale. Health Canada's sources of information about adverse events include industry (which must operate its own surveillance systems as required by the Regulations), health care professionals, patients, consumers, and other international regulators. Based on the results of post-market surveillance, Health Canada may be required to take actions, either by itself or in co-operation with the manufacturer. These actions could include informing the public of safety concerns, recalling a device, or suspending or cancelling the licence for the device and removing it from the market completely.

This structure anchor is used to securely reattach soft tissue such as tendons and ligaments to the bone joint.

Source: Smith and Nephew Inc.

2.85 The purpose of post-market surveillance is to continue to gather information on the safety and therapeutic effectiveness of medical devices in the "real life" marketplace. This builds on the information about safety and therapeutic effectiveness established during the pre-market testing, for example, investigational testing or laboratory testing. The information collected from pre-market testing can be limited because it is restricted. For example, investigational tests occur in a controlled setting with carefully selected subjects for a limited amount of time. Once the product is available to a much larger and unrestricted population for a much longer period of time, new information about safety and therapeutic effectiveness becomes available. This information is more revealing about the actual health and safety risks. Since this new information permits the ongoing assessment of products in wide use by a large number of Canadians, good post-market surveillance systems are an essential element of Health Canada's processes to manage risk.

2.86 The Medical Devices Review Committee acknowledged the importance of post-market surveillance. The Committee observed the weaknesses in Health Canada's then-current system of collecting only voluntary reports of adverse events from manufacturers, health care professionals, and the public. As a result, the Committee suggested a combination of active collection of reports about adverse events from these groups and proactive monitoring of patients through mechanisms such as device registries. In its Development Plan, Health Canada committed to completing a feasibility study of these recommendations. Since then, Health Canada has completed several studies to assess weaknesses in post-market surveillance and options for addressing these weaknesses. Also, since the release of the Committee's report, a number of other reports—including those of the Commission of Inquiry on the Blood System in Canada in 1997 and the Working in Partnership–Drug Review for the Future in 1992—have also observed how important good post-market surveillance is and have made similar recommendations to those respective programs.

2.87 We found that Health Canada has taken only limited action to improve the way it collects, analyzes, and interprets information about adverse events. In terms of improving collection, the only significant action taken by Health Canada has been to make it mandatory, through the Regulations, for manufacturers and importers to report in a timely manner serious adverse events that come to their attention. While it is recognized that health care professionals are most often the first to observe adverse events, we found that Health Canada has done little work to increase the number and quality of reports received from them. As a result, Health Canada is not able to adequately identify adverse events.

2.88 Weaknesses in the analysis and interpretation of adverse events also continue to exist. Currently, when Health Canada receives a report about an adverse event, the information is entered into the national incident database. When Health Canada receives a complaint, it verifies details of the incident with the user and, if appropriate, investigates to determine whether corrective action is necessary. For adverse events or complaints identified as a particular concern, health hazard evaluations and laboratory evaluations are completed. However, there is no proactive system for identifying patterns in reports or complaints that could signal a serious safety concern.

2.89 Exhibit 2.8 compares the rates of reporting of adverse events related to medical devices in Canada, the U.S., and the UK and indicates the lower level of reporting in Canada relative to the other countries. Health Canada acknowledges that its lower levels of reporting are due, in part, to its limited activities in the area of post-market surveillance.

2.90 As a result of the studies to assess weaknesses in post-market surveillance, Health Canada is aware of the gaps and weaknesses in its approach and the importance of correcting them. However, very little has been done to correct them. Exhibit 2.9 provides a number of possible options available to Health Canada. Each is currently being piloted or used elsewhere with some success, including Health Canada's Drug Program and the medical devices programs of the U.S. and the UK.

Exhibit 2.8 Reporting adverse events of a medical device in Canada, the U.S., and the UK, 2002

	Canada	U.S.	UK
Mandatory—manufacturer	730	141,000	2,000
Mandatory—hospitals	0	2,500	0
Voluntary	270	3,500	6,750
Total	**1,000**	**147,000**	**8,750**
Population (millions)	30	288	59
Rate per million	33	510	148

Source: Health Canada, U.S. Food and Drug Administration, UK Medicines and Healthcare Products Regulatory Agency

Exhibit 2.9 Options available to Health Canada to improve post-market surveillance

Sentinel systems (U.S.)—An active surveillance system which currently collects adverse events information from approximately 180 sentinel health care facilities (select health care facilities that volunteer to participate fully). Once fully implemented this program will include 250 sentinel facilities.

Liaison officers (UK)—A network of surveillance officers that are stationed in each hospital with responsibility for actively collecting adverse-events information and providing that information to the Medicines and Healthcare Products Regulatory Agency.

Active surveillance systems (Canada)—Health Canada is currently piloting an active surveillance system for pediatric drugs. Health Canada has developed arrangements with specific health care professionals and facilities that deal with children to have them actively collect information on adverse drug events and submit it to Health Canada.

Registries (Sweden)—Registries are data bases where clinicians provide data regarding patients who have the clinical conditions of interest. Data includes diagnosis and history, treatment, and related variables. Patient outcomes are monitored with a view to establishing the relationship between treatment and outcomes.

Environmental scanning (UK)—A regular and active scan of relevant domestic and international media.

Inspection of manufacturers' post-market surveillance systems (U.S.)—Inspection to ensure: that manufacturers are operating post-market surveillance systems that are adequate to identify adverse events; and that manufacturers are reporting all serious adverse events to the government.

Integrated adverse-events reporting systems (Canada)—Canada will use the U.S. Adverse Events Reporting System software to create its own database for Canadian adverse events. The Canadian database will be supplemented by de-identified U.S. data (data that contains no personal information) on a regular basis through downloads of the U.S. data.

Source: U.S. Food and Drug Administration, UK Medicines and Healthcare Products Regulatory Agency, Health Canada

Communication of safety concerns may not be adequate

2.91 The government's responsibility related to safety concerns does not end with identifying concerns. Health care professionals and the public expect that the government will communicate safety concerns in a timely manner to those who need to know. Communication provided to the wrong people or received too late may not prevent the reoccurrence of an adverse event.

2.92 **Notifications of safety concerns.** The Medical Devices Review Committee observed that Health Canada's approach to communicating safety concerns was weak. As a result, it made three recommendations in this area: develop a communications plan, develop a strategy to expand its communications, and improve its communication methods.

Listserv—An electronic communication system that provides subscribers with access to messages, especially related to topics of special interest.

2.93 We observed that Health Canada has a number of tools to communicate safety concerns to health care professionals and the public. These include Web site notices, a newsletter, a listserv, and letters to health care professionals. Health Canada also monitors high-risk recalls conducted by manufacturers to help ensure their effectiveness.

2.94 However, we found that Health Canada has never developed a communications plan or a communications strategy for medical devices. As such, it cannot be confident that its methods of communication are the best, that its communications are reaching the right people, or that its communications are timely.

2.95 We conducted a survey of biomedical engineers at 19 major urban hospitals in Canada, representing most urban hospitals in Canada. We solicited their views about Health Canada's approach to communicating safety concerns. The individuals surveyed are responsible for investigating adverse events related to medical devices in their respective hospitals, as well as reporting adverse events related to medical devices to manufacturers and/or to Health Canada. Further, they are responsible for sharing with others in their hospital information that they receive about safety concerns. In general, those surveyed identified concerns about the timeliness of communication and the limited number of communications they receive from Health Canada. All of the 19 engineers surveyed stated that they do not rely on Health Canada as their primary source of information on safety concerns. When asked if the communications they received from Health Canada were timely, 12 answered no.

What biomedical engineers said about how Health Canada communicates safety concerns

"We don't even get one-tenth of what is going on in the marketplace from Health Canada."

"When we do get notices from Health Canada, we usually already know about it."

2.96 **Tracking of certain implantable devices.** The purpose of tracking certain implantable devices is to enhance the ability of the manufacturer to locate the patient if the implantable device is recalled.

2.97 We expected Health Canada to have a mechanism to track certain implantable devices in order to help ensure that patients are informed of any safety concerns. We found that for certain implantable devices the Regulations require health care professionals to complete two copies of a registration card once a device is implanted; one copy goes to the manufacturer and the other goes to the patient. This approach should allow the manufacturer to be able to locate the patient using the information on the registration card in the event of a recall.

2.98 However, we also found that to respect the *Privacy Act*, health care professionals cannot identify the patient on the registration card unless they have received informed consent from the patient to do so. If health care professionals do not request consent, they cannot provide patient contact information and the manufacturers will not have the necessary information to contact the patient. As a result, patients may not be notified of a serious problem or recall related to their implanted device.

2.99 There are a number of possible options available to address this weakness. One is to use device registries; another is to follow the U.S. approach to dealing with patient information for those devices subject to tracking. In the U.S., the regulations do not require that health care professionals obtain signed informed consent to provide patient contact information. As a result, they can provide manufacturers with all the information needed to contact patients. Exhibit 2.10 discusses the automobile recall process. While the two industries are not directly comparable for a number of reasons, including the fact that information about personal health is more private and sensitive than information about vehicle ownership, the recall process for automobiles provides an interesting contrast to recalls of medical devices.

Exhibit 2.10 The automobile recall process

Under the *Motor Vehicle Safety Act*, if a car manufacturer needs to issue a recall, it must notify all current owners.

The manufacturer first notifies all those individuals who have registered their car purchase with them. If it no longer has current information, the manufacturer is provided with access (through the Canadian Council of Motor Transportation Administrators) to the provincial licence registries to obtain the personal information necessary to establish contact. If the manufacturer is still unable to notify all owners, it must give notice of the defect by publication in two major daily newspapers covering six regions for five consecutive days.

Source: *Motor Vehicle Safety Act*

2.100 Recommendation. Health Canada should ensure that it manages the risks and benefits related to medical devices after they are available for sale. More specifically, it should

- engage in active inspection of industry operations at the post-market phase to verify compliance with the Regulations;
- take a more active approach to dealing with unlicensed devices by ensuring that they are easy to identify and that actions taken against sellers of unlicensed devices will discourage this practice;
- improve the collection, analysis, and interpretation of post-market surveillance information by increasing the number and quality of adverse events reports collected and by improving its analytical and interpretive capability; and
- improve its approach to communication of safety concerns so that those who need to know are informed in a timely manner.

Department's response. Agreed. Health Canada will continue to review its current level of activity in relation to these post-market issues and develop an action plan to address the gaps. Health Canada will review all options and determine which options best mitigate the risks associated with medical devices in the post-market phase. Specific responses to this recommendation will be considered in the context of the departmental response to the recommendation in paragraph 2.122. Health Canada's goal for the development of the action plan is Spring 2005.

Reuse of single-use devices needs to be better managed

Critical-contact single-use devices—Devices that come into contact with blood or normally sterile body cavities by penetrating the skin or mucous membrane, such as cardiac catheters or urinary catheters.

2.101 In Canada, it is common for health care facilities to reuse single-use devices. A 2001 nation-wide survey indicated that 37 percent of acute-care hospitals reused critical-contact single-use devices. This survey was conducted jointly by one of the advisory committees to the Conference of Deputy Ministers of Health (federal and provincial) and a research contractor. The surveyors contacted 802 acute-care hospitals; 461 responded. The reuse of single-use devices is different from the reuse of devices designed for multiple uses because single-use devices were not intended to be reused. Thus, their reuse creates a number of potential risks that include poor functioning after multiple uses or reprocessing, as well as concerns about sterilizing and disinfecting medical devices properly. Other concerns include the lack of informed consent by the patient and the liability of the reuser should something go wrong because of reuse. The main reason that single-use devices are reused is to reduce costs.

Reprocessor of single-use devices—Anyone who sterilizes or disinfects a used single-use device so it can be reused. This can include a company specializing in reprocessing or a hospital that reprocesses its own devices.

Reprocessing of single-use devices—The sterilization or disinfection of a used single-use device so that it can be reused.

2.102 Recently the U.S. introduced new regulations covering the reuse of single-use devices to address these risks. Basically, reprocessors of single-use devices are subject to all the regulatory requirements applicable to the original device manufacturer. Under the U.S. Food and Drug Administration's new regulations for reprocessing of single-use devices, all single-use devices that required approval initially must now have pre-market approval for reprocessing. Should the U.S. Food and Drug Administration be satisfied that safety and therapeutic effectiveness of the device can be preserved with reprocessing, approval will be given.

2.103 Because the reuse of single-use devices can put the health and safety of Canadians at risk and because Health Canada is one of the entities responsible for protecting the health and safety of Canadians, we expected that it would take action to deal with this issue. While we recognize that this issue is a shared responsibility among various jurisdictions and professions, it is important that Health Canada as the federal regulator take action to manage the health and safety risks related to the reuse of single-use medical devices.

2.104 However, we found that Health Canada has not developed a position on managing the risks related to the reuse of single-use devices, although very recently it began examining its authority to regulate reuse practices. As a result, Canadians are not being protected from the health and safety risks created by the reuse of single-use devices. Canada's failure to develop a position on this issue has created a regulatory vacuum (Exhibit 2.11).

2.105 **Recommendation.** Health Canada should take action, such as regulating reprocessed single-use devices, to manage the health and safety risks related to the reuse of single-use medical devices.

Department's response. Agreed. The safety of medical devices in Canada is a shared responsibility, with some authority falling under the jurisdiction of the provinces and territories. Health Canada will undertake a review of the current federal statutory/regulatory authorities to determine its ability to

Exhibit 2.11 Canada does not have a position on the reuse of single-use devices

The U.S. regulations for reprocessing of medical devices are quite recent, and to date, only a few devices have been granted pre-market approval. Critical-contact single-use devices (see margin definition on page 26) are among those that have not yet been approved. Canadian hospitals are interested in having devices, including critical-contact devices, reprocessed by American reprocessors. However, before the U.S. will allow shipment of any "unapproved" reprocessed devices out of the U.S. and back to Canadian hospitals, it needs a letter from Health Canada stating that the device "...complies with the laws of that country" (as required by the U.S. Food and Drug Administration *Export Reform and Enhancement Act of 1996*).

As a result, Health Canada has prepared a "Letter of No Objection" for reprocessors that may want to import reprocessed devices into Canada. To date this letter has not been used. The letter states that Health Canada is aware that the reprocessor has reprocessed devices belonging to the Canadian health care facility. It further states that Health Canada is aware that these devices have not been approved by the U.S. Food and Drug Administration for reprocessing. And finally, the letter notes that the shipment of the reprocessed devices does not contravene Canadian law. In essence, the letter is not stating that Health Canada agrees with the practice but rather that the practice is not breaking Canadian law. Thus, devices that have not yet been approved for reprocessing by the U.S. Food and Drug Administration could be reprocessed and imported to Canadian hospitals.

Source: Health Canada, the U.S. Food and Drug Administration, and other sources

regulate the reprocessing of single-use medical devices. Additionally, Health Canada will consult with stakeholders, in particular its provincial and territorial partners, who share in the responsibility for the delivery of health care, to determine the best approach to minimize the health and safety risks related to the reuse of single-use medical devices. Health Canada's goal for completion of these consultations is Spring 2005.

Capacity issues exist in the program

2.106 **Cost recovery**. The Medical Devices Review Committee recommended implementing a cost recovery program, with fees collected for the pre-market approval of devices to provide resources for improving the Medical Devices Program.

2.107 Between the Committee's report in 1992 and the introduction of the Medical Devices Regulations in 1998, Health Canada participated in the 1994 government-wide Program Review. During Program Review, it was concluded that the services provided by the Medical Devices Program were a private benefit, and therefore private beneficiaries should pay a portion of the cost of the service. It was determined that fees could be charged and, as a result, the Program was required to give up $5.6 million of its government funding.

2.108 Health Canada initially introduced cost recovery for medical devices in 1996, immediately after Program Review. However, it expanded its cost recovery in 1998 with the introduction of the Medical Devices Regulations. The Regulatory Impact Analysis Statement accompanying the 1998 Fees in

Respect of Medical Devices Regulations noted that fees had been set so the Program could recover $7.7 million per year.

Direct costs—Costs of the Program that are directly related to the service activity, for example, the cost of an evaluator to evaluate an application.

Indirect costs—Costs of the Program that are not directly related to the service activity, for example, the cost of negotiating international agreements.

2.109 However, we found that because of problems in setting fees, in 2002–03 the actual revenue for direct costs was $4.6 million and for indirect costs was $1.7 million, for total revenues of $6.3 million. This is significantly below what was estimated as necessary. We determined that this shortfall happened because the estimate of the direct and indirect costs of the program had been significantly below the actual costs; then the fees were not set high enough to recover the estimated costs; and then the fee structure was changed after negotiations with the industry, resulting in even less revenue. Further, we found that because of Program Review, cost recovery became a means to replace lost government funding and not a means of collecting funds to improve the Program.

2.110 Because of this funding shortfall, the level of resources engaged in pre-market evaluation activities has been significantly below the level Health Canada estimates is needed to effectively deliver these activities. It has estimated that it requires 97 full-time-equivalent staff for its pre-market activities, including managing its quality-systems activities and class II, III and IV device-licensing activities. However, it currently has only 58 employees.

2.111 **Recommendation**. Health Canada should resolve the problems in its cost recovery program. It should determine the actual costs of the program and set fees based on those costs.

Department's response: Agreed. Health Canada is committed to a cost recovery program consistent with the Treasury Board Secretariat's External Charging Policy, including required consultation with industry. Health Canada is currently implementing its 2002 Cost Recovery Initiative 2 Action Plan, part of which is the development of a revised costing model that will allow Health Canada to more accurately determine the costs of delivering its regulatory activities, appropriately price its fees, more accurately estimate the revenues, and more fully report on its activities. Health Canada initiated the development of a costing model in 2003, with a goal of providing revenue and cost information through the Performance Report in 2005.

A-base funding—Funds that are provided to Health Canada to support ongoing programs.

Revenue—Fees collected from the industry for services provided to it.

Funding for special initiatives—Additional resources that are requested by a minister and approved by the Cabinet or the Treasury Board for special initiatives.

Resource reallocations—Funds that have been collected through a "levy" on programs within the Department and reallocated within the Department to support departmental priorities.

2.112 **Financial resources.** Exhibit 2.12 provides a breakdown of funding sources in 2002–03 for direct costs only. Indirect costs are included elsewhere in Health Canada's costs. The Medical Devices Program receives funding from four sources: A-base funding, revenue, funding for special initiatives, and resource reallocations.

2.113 In its 1992 report, the Medical Devices Review Committee concluded that Health Canada did not have enough resources to support the necessary program changes. As previously discussed, the Committee recommended the introduction of cost recovery as a means to provide resources for improving the Program. It also recommended that once the new program was ready to be introduced, Health Canada should provide an additional 40 staff positions (representing about $1.8 million in 1992) and $2.2 million for operational costs, for a total of about $4.0 million in 1992 dollars. Health Canada was also advised to reassess its resource requirements after two years. This would have brought the total amount of A-base funding required for the new program to $7.4 million (existing 1992 A-base of $3.4 million plus additional A-base of $4.0 million). Health Canada did not respond to this recommendation in its Development Plan.

2.114 In the 1998 Regulatory Impact Analysis Statement accompanying the Fees in Respect of Medical Devices Regulations, it was noted that fees had been set so the program would collect revenue of $7.7 million per year. It was further noted that this amount, combined with the A-base funding that remained after the 1994 Program Review money was taken away, was expected to be sufficient to deliver the new Medical Devices Program. The 1998 A-base funding was about $1.5 million per year.

2.115 As noted in Exhibit 2.12, the A-base funds allocated to the Medical Devices Program in 2002–03 were $403,000. This was significantly below the amounts that the Medical Devices Review Committee estimated were necessary for a new Program. The Committee estimated an amount of $1.8 million ($7.4 million as suggested, less $5.6 million lost as part of 1994 Program Review). The 2002–03 A-base funds were also significantly below the $1.5 million that Health Canada estimated was necessary when the new Program was actually introduced in 1998.

2.116 **Erosion of capacity.** As required, the Department conducts an annual resource reallocation exercise in which it collects money in the form of a levy from each Branch. The funds are then reallocated to departmental priorities as determined by senior management at Health Canada. The levy is passed on to programs within the branches. As required, the branches also conduct a resource-reallocation exercise in which they collect money from each program in addition to the money paid to cover the departmental levy, and then reallocate it to branch priorities as determined by branch management.

2.117 We determined that between these two levies, the Medical Devices Program lost $424,000 in 2002–03. We also determined that the Program received $514,000 from the reallocation for specific activities. Most of its other priority projects, which include a feasibility study of a high-risk cardiac implant registry and a breast implant registry, were not considered priorities for funding. This process creates instability in funding and erodes the Program's ability to carry out its responsibilities.

2.118 Also of concern is that for the year 2003–04, levies were applied to funding for special initiatives and to revenue from fees paid by industry for services. Additional funds provided by the Cabinet or the Treasury Board are for specific initiatives. Funds taken in the form of levies and redirected no longer directly support the activities that the Cabinet or the Treasury Board agreed to support. Further, revenues from fees for a service that are taken and redirected are no longer going directly to support the delivery of that service.

2.119 Further, funds provided to the Health Products and Food Branch to cover collective bargaining salary increases in its programs were held back at the Branch level and not provided to the programs. The programs were forced to cover the collective bargaining increases out of their annual budgets. At the end of the year, any salary deficits in the programs were covered by the Branch from funds that included the collective bargaining increases that had been held back.

2.120 **Balancing resources.** The Medical Devices Review Committee recommended that the Medical Devices Program balance its focus between pre-market and post-market activities. In its specific observations and recommendations, the Committee presented suggestions for activities in both areas that would achieve this goal. However, while some weaknesses remain in the pre-market activities, the most significant gaps and weaknesses are in the post-market activities. Exhibit 2.12 provides a comparison of resources allocated to pre-market and post-market activities.

Exhibit 2.12 Funding sources for direct costs and full-time equivalents allocated to pre-market and post-market activities in 2002–03

Funding ($ thousands)	Pre-market	Post-market	Total
A-base funding	0	403	**403**
Revenue	2,677	1,966	**4,643**
Special initiatives	1,726	510	**2,236**
Resource reallocations	21	69	**90**
Total	**4,424**	**2,948**	**7,372**
Full-time equivalents	58	37.5	**95.5**

Source: Health Canada

2.121 The funding allocated to post-market activities is significantly less than is allocated to pre-market activities. Because of the limited resources available to engage in post-market activities, the 37.5 staff equivalents involved in this activity are significantly below the 73 staff that Health Canada has estimated it needs for a good post-market system.

2.122 **Recommendation**. Health Canada should either provide adequate human and financial resources to allow for delivery of the Medical Devices Program as it is designed or redesign the Program to allow health and safety risks to be adequately managed in other ways that require fewer resources.

Department's response. Agreed. Health Canada will undertake a review of the Medical Devices Program in consultation with stakeholders to determine the appropriate level of program delivery, the appropriate program design, the associated resource requirements, and possible funding sources. This review will be supported by the findings and recommendations stemming from concurrent activities in such areas as the cost recovery program and performance measurement framework (noted in the responses following paragraphs 2.111 and 2.127 respectively). Health Canada's goal for completion of this review is Summer 2005.

2.123 **Recommendation.** To inform Parliament, in two years Health Canada should assess its progress and challenges in making changes to the Medical Devices Program. The results should detail what improvements were made and how they were made as well as the gaps that remain and the reasons why they remain. Significant findings should be included in Health Canada's annual reporting to Parliament.

Department's response: Agreed. Health Canada's response to the Medical Devices Review Committee's report was the Development Plan for an Improved Medical Devices Regulatory Program. Health Canada will assess, in two years, its progress and challenges in making improvements to the Medical Devices Program based on this response and include significant findings in its annual reporting to Parliament.

Evaluation, performance measurement, and reporting to Parliament

2.124 Program evaluation and ongoing measurement of performance tell management what has worked to produce desired results and what has not. The government needs this information for planning and setting priorities. Reporting performance information to Parliament enables parliamentarians to make informed decisions about the program.

2.125 We expected that Health Canada would adequately evaluate the Program as well as measure and report the results achieved. Given the challenges that the Program faces and the gaps and weaknesses that exist, we expected Health Canada to bring these issues to the attention of Parliament in its reports.

2.126 We found that the Medical Devices Program has not been evaluated recently. Health Canada has developed and is implementing a performance management framework, which includes performance indicators relevant to the Medical Devices Program. However, presently the only performance measures used at Health Canada are the amount of time taken to authorize device licences and the number of new and amended licences authorized and renewed annually. Our review of Health Canada's previous three reports on plans and priorities and its performance reports, including the 2002–03 Performance Report, found minimal mention of the targets, performance, and weaknesses of the Medical Devices Program. When performance is weak, as is the case in the Medical Devices Program, parliamentarians need to know it is weak and why it is weak so they can support needed improvements.

2.127 **Recommendation.** Health Canada should adequately evaluate, measure, and report the results of the Medical Devices Program—both its achievements and challenges.

Department's response. Agreed. Steps are currently being taken to improve our ability to report program results. Health Canada is developing a measurement framework for the Medical Devices Program to provide a balanced view of performance, and it commits to enhancing public reporting on our actions. Health Canada's goal for completion of this measurement framework is Spring 2005.

Conclusion

2.128 Equal and timely access to quality health care is a priority for Canadians. This includes timely access to medical devices, which play an important role in all stages of the delivery of quality health care.

2.129 The Medical Devices Review Committee was established in 1991 to formulate recommendations to the Minister of Health concerning the regulation of medical devices and associated activities. Health Canada responded to the report and, with additional help from the Committee, prepared a Development Plan for an Improved Medical Devices Regulatory Program, proposing changes to its Medical Devices Program. Health Canada also consulted with stakeholders on the proposed changes. Because Health Canada responded to the report and made efforts to implement changes, we have used the Department's response as the standard against which we have measured the Medical Devices Program. The Department has accepted that we are using this standard.

2.130 In 1998 Health Canada introduced new regulations, introduced some new activities, and made improvements to some existing activities. However, a number of gaps and weaknesses remain, particularly in its activities to manage risks and benefits after devices are approved for sale. Health Canada is aware of these gaps and weaknesses but has made limited effort to address them.

2.131 More specifically, we are concerned that Health Canada does not

- play a role in the conduct of investigational tests once they have begun;
- proactively inspect industry operations at the post-market phase to verify that they are in compliance with the Medical Devices Regulations;
- have a system that provides sufficient information on adverse events, conduct adequate analysis of the adverse-events information it does collect, or communicate safety concerns in a timely manner;
- act to address the health and safety risks related to the reuse of single-use devices; and
- act to improve timely access to all available medical devices.

2.132 Limited financial and human resources and limited progress in advancing international regulatory co-operation prevent Health Canada from delivering the Medical Devices Program as designed. Failure to discharge its responsibilities under this Program compromises Health Canada's ability to protect health and safety, which could translate into a growing risk—risk of both injury and liability.

2.133 While elements of the Program are acceptable, there are significant shortfalls, which indicate that the current program is not sustainable. Therefore Health Canada must make a choice. It must provide adequate resources to deliver the Program as designed, based on the Committee's report or redesign the Program and the Regulations to allow health and safety risks to be managed in a way that requires fewer resources.

2.134 Health Canada needs to improve its evaluation, measurement, and reporting of results of its Medical Devices Program. This is especially important given the questions about whether to continue with the current Program or redesign it.

2.135 Our final concern relates to the Medical Devices Program's ability to deal with future demands. It is expected that medical devices will become increasingly complex and that the medical devices industry will grow in both size and importance. Health Canada will need to adapt its program to accommodate this increase in the number and complexity of devices. The gaps and weaknesses that exist now raise concerns about how it will manage in the future.

About the Audit

Objectives

The objectives of this audit are to determine whether Health Canada adequately

- manages the risks and benefits related to safety and therapeutic effectiveness of medical devices available in Canada;
- identifies weaknesses in the Medical Devices Program and takes action to address them; and
- measures and reports the results achieved by the Medical Devices Program.

Scope and approach

The focus of this audit was Health Canada's Medical Devices Program managed by the Health Products and Food Branch, and in particular the Program activities directed at class II, III, and IV medical devices.

We examined the activities Health Canada engages in to discharge its responsibilities. We reviewed the 1992 report issued by the Medical Devices Review Committee and the Development Plan for an Improved Medical Devices Regulatory Program prepared by Health Canada in response to the Committee's report. We also reviewed the documentation from the consultations with stakeholders that took place prior to the introduction of the new Regulations. We made comparisons with the medical devices programs in the U.S. and the UK and with the Drugs Program delivered by Health Canada. Further, we considered the impact of the Medical Devices Program's human and financial resources on Health Canada's ability to adequately discharge its responsibilities.

We carried out extensive interviews with Health Canada staff involved in the Medical Devices Program. We met with several different stakeholder groups. We reviewed documentation, including legislation, regulations, program documents, studies, public communication, and device evaluation, hazard analysis, and investigation files. Finally, we met with staff involved in the medical devices programs of the U.S. Food and Drug Administration and the UK Medicines and Healthcare Products Regulatory Agency, and with Health Canada staff involved in the Drugs Program.

Criteria

We expected that Health Canada would

- have an approach to identify, manage, and communicate risks and benefits to Canadians in a timely, efficient, and effective manner;
- have designed and implemented a regulatory process to manage the risks related to the safety and therapeutic effectiveness of medical devices;
- have adequate resources, both human and financial, to discharge its responsibilities;
- work co-operatively with other international jurisdictions to improve the efficiency of the Medical Devices Program;
- identify gaps and weaknesses in the Program and have plans to address them;
- develop plans to amend regulations and adapt the program to new and emerging circumstances; and
- adequately measure and report the results achieved by the Medical Devices Program.

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Chapter 3
National Security in Canada—
The 2001 Anti-Terrorism Initiative

Office of the Auditor General of Canada

The March 2004 Report of the Auditor General of Canada comprises seven chapters, a Message from the Auditor General, and Main Points. The main table of contents is found at the end of this publication.

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Ce document est également disponible en français.

© Minister of Public Works and Government Services Canada 2004
Cat. No. FA1-2004/1-3E
ISBN 0-662-36243-8

Chapter

3

National Security in Canada

The 2001 Anti-Terrorism Initiative

All of the audit work in this chapter was conducted in accordance with the standards for assurance engagements set by the Canadian Institute of Chartered Accountants. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.

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National Security in Canada
The 2001 Anti-Terrorism Initiative

Main Points

3.1 In response to the September 11 terrorist attacks on the United States in 2001, the Canadian government took several steps: It established the Ad Hoc Cabinet Committee on Public Security and Anti-Terrorism, chaired by the Deputy Prime Minister; mobilized the military, the RCMP, and the public service to manage the initial crisis; and then developed a long-range initiative to improve Canadian security. In the 2001 Budget, the government allocated $7.7 billion in new funds to be spent over the next five years on the Public Security and Anti-Terrorism initiative to enhance security for Canadians.

3.2 Our audit examined the overall management of the Public Security and Anti-Terrorism initiative. We also examined the co-ordination of intelligence among departments and agencies and their ability to provide adequate information to enforcement personnel. In addition, we examined selected issues in greater detail—the interoperability of security and intelligence information systems; fingerprint identification; and the assessment of airport workers who require clearances to restricted areas. Other countries, including the United States, have examined similar areas and reported findings comparable with those of our audit.

3.3 We found that the government had developed management systems to direct and control spending and reporting on activities under the initiative. The vast majority of funds allocated in the 2001 Budget have been channelled to priority areas. In addition, the Treasury Board Secretariat is tracking spending and attempting to assess the security improvements achieved by the initiative. However, we found that the government did not have a management framework that would guide investment, management, and development decisions and allow it to direct complementary actions in separate agencies or to make choices between conflicting priorities.

3.4 The government as a whole failed to achieve improvements in the ability of security information systems to communicate with each other. Consequently, needed improvements will be delayed by several years. Moreover, even as the government was launching programs that would create new needs for fingerprint identification, projects that would have helped it to deal with the increased demand were not included in the initiative.

3.5 We also found deficiencies in the way intelligence is managed across the government. A lack of co-ordination has led to gaps in intelligence coverage as well as duplication. The government as a whole did not adequately assess intelligence lessons learned from critical incidents such as September 11 or develop and follow up on improvement programs. Individual agencies have created new co-ordinating mechanisms, but some departments are still not participating in them.

3.6 We found gaps and inconsistencies in the watch lists used to screen visa applicants, refugee claimants, and travellers seeking to enter Canada. There is no overall quality control of this vital function, which is spread over several departments and agencies. No one monitors delays in the entry or the quality of the data on watch lists.

3.7 Finally, criminal intelligence data are not used to screen applicants for clearance to restricted areas at airports, meaning that security clearances are issued without checking applicants for criminal association. Transport Canada is not provided with all the information available to police and therefore has issued restricted area clearances to many individuals whose reliability must be questioned. Unless air transportation workers with access to aircraft are reliable, spending on passenger and cargo security will be of reduced value.

The departments and agencies have responded. In general, they have agreed with our recommendations although commitments toward remedial action are sometimes vague. We found that the responses from the Canada Border Services Agency and Public Safety and Emergency Preparedness Canada provide a clear picture of their intentions.

Introduction

The impact of September 11

3.8 On September 11, 2001 the United States suffered an unprecedented terrorist attack that destroyed the World Trade Center, damaged the Pentagon, destroyed four civilian airliners, and killed thousands of citizens. The immediate effects on Canada were the need to deal with the shutdown of civil air transport and look after passengers on grounded airliners; heightened border security; and a sudden sense of personal and economic insecurity.

3.9 The crisis period lasted several months, during which the federal government had to sustain internal and border security operations at a high level. Defence, intelligence, police, and border control agencies worked to full capacity. Ministers and senior managers sought to deal with policy and budget issues on an urgent basis, while at the same time drafting emergency legislation and guiding it through Parliament.

3.10 In the longer term, the federal government has had to develop policies and programs to deal with the threat of terrorism not only to Canada directly but also to the United States and the rest of the world.

3.11 **Management of national security.** Unlike the United States—but similar to both the United Kingdom and Australia—Canada had not consolidated domestic security agencies under a single department until 12 December 2003. Instead, like its Commonwealth colleagues, it relied on Cabinet and co-ordinating agencies to manage security affairs. This audit assessed the situation prior to the 2003 reorganization.

3.12 On 12 December 2003, the Prime Minister announced significant changes to the structure of parliamentary committees, departments, and agencies. The principal changes involving national security are the following:

- A new department, Public Safety and Emergency Preparedness Canada, has been created from the former Solicitor General Canada. The new department includes the Office of Critical Infrastructure Protection and Emergency Preparedness, transferred from National Defence.
- The Canada Border Services Agency, reporting to the Minister of Public Safety and Emergency Preparedness, comprises the Customs Branch from the former Canada Customs and Revenue Agency, the intelligence and enforcement sections from Citizenship and Immigration Canada, and the border inspection function of food, plant, and animal health from the Canadian Food Inspection Agency.
- The new position of National Security Advisor to the Prime Minister in the Privy Council Office will co-ordinate integrated threat assessments, help strengthen interagency co-operation, and assist in the development of an integrated policy framework for national security and emergencies.
- The Minister of Transport is now responsible for security in all transportation sectors.

- A new Cabinet Committee on Security, Public Health and Emergencies will manage national security and intelligence issues and activities and government-wide responses to public health, national disasters, and security emergencies. It will replace the Ad Hoc Committee on Public Security and Anti-Terrorism.

3.13 At the time of our audit, the government delivered national security programs through many departments and agencies. In general, national security programs include national defence, policing and federal law enforcement, intelligence, border control, transportation security, critical asset protection, and disaster and emergency management. The principal organizations involved in program delivery are detailed in Exhibit 3.1.

3.14 Until December 2003, no single minister below the Prime Minister was responsible for Canada's security. The organizations involved in security reported to their respective ministers, who were accountable for their activities. Ultimately the Prime Minister was, and remains, accountable for the security of the country and therefore provides broad guidance. The Prime Minister usually chaired the annual Meeting of Ministers on Security and Intelligence. Other Cabinet committees such as the Cabinet Committee on Social Union made decisions when security and intelligence involved broader social policy issues. The new organization consolidates many of these departments and agencies under a single minister.

3.15 In late September 2001, the Prime Minister established the Ad Hoc Cabinet Committee on Public Security and Anti-Terrorism to review policies, legislation, regulations, and programs across the government in order to strengthen all aspects of Canada's approach to fighting terrorism and ensuring public security. The Chair of the Committee (the Deputy Prime Minister) was charged with co-ordinating overall elements of the government's response to the events of September 11. Members of the Committee were the Solicitor General and the ministers of Finance, National Defence, Transport, Foreign Affairs, Justice and Intergovernmental Affairs, National Revenue, Citizenship and Immigration, and Health.

3.16 This ad hoc committee, like other ad hoc committees of Cabinet, was established to address time-sensitive issues that cut across the mandates of several ministers. The Committee provided advice to the Prime Minister and Cabinet and remained active in discussing national security issues and providing general policy direction, but it did not regularly make program or policy decisions. These were normally referred to permanent committees of Cabinet. The Ad Hoc Committee on Public Security and Anti-Terrorism continued to meet on a regular basis during our audit. It has now been replaced by the Cabinet Committee on Security, Public Health and Emergencies.

3.17 Below the ministerial level, the Privy Council Office—the Prime Minister's "department"—co-ordinates bureaucratic efforts. The Clerk of the Privy Council chairs the Interdepartmental Committee on Security and Intelligence (ICSI), which includes the deputy heads of the main agencies involved and is the main executive forum that reviews major policy issues

Exhibit 3.1 Principal organizations involved in national security program delivery, at the time of our audit*

Organizations	Program delivery
National Defence **Canadian Forces**	• provides defence of country • deployed overseas to advance and protect Canadian values and interests • responsible for JTF2, a high-readiness counter-terrorism unit that rescues hostages or undertakes other action required in response to a terrorist incident • maintains a chemical-biological-nuclear company to respond to attacks against Canada
Communications Security Establishment	• collects and analyzes foreign signal intelligence • helps ensure the federal government's own telecommunications are secure
Office of Critical Infrastructure Protection and Emergency Preparedness	• provides national leadership to protect Canada's physical and cyber infrastructure against threats (natural disaster or purposeful attack) • ensures civil emergency preparedness
Solicitor General Canada	• oversees public safety and provides policy direction to its agencies • responsible for the National Counter-Terrorism Plan, which outlines roles and responsibilities for managing terrorist incidents
Royal Canadian Mounted Police	• enforces federal laws as Canada's national police service • provides contract policing to most provinces, the three northern territories, many municipalities, and First Nations communities • provides forensic services and criminal intelligence to Canadian and foreign police • responsible for primary investigation of criminal offences related to terrorism and espionage • protects Governor General, Prime Minister, and visiting foreign dignitaries • provides on-board security on selected civil airline flights
Canadian Security Intelligence Service	• investigates, analyzes, and advises government departments and agencies on potential threats to Canada's national security • investigates political violence and terrorism, espionage and sabotage, and foreign-influenced activities detrimental to Canadian national interests, such as interference with ethnic communities in Canada • provides security assessments for all federal government personnel requiring a security clearance (except the RCMP); transportation workers; and immigration, citizenship, and refugee applicants
Foreign Affairs and International Trade	• manages day-to-day conduct of relations with foreign states and peoples • protects Canadians and Canadian government facilities abroad • handles terrorism incidents abroad involving Canadians • manages such issues as the expulsion of foreign diplomats from Canada for security reasons • through its Security and Intelligence Bureau provides Minister with foreign intelligence to support policy and operational decisions and advises Minister on intelligence activities

*On 12 December 2003, the Prime Minister announced significant changes to these organizations (see paragraph 3.12).

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*On 12 December 2003, the Prime Minister announced significant changes to these organizations (see paragraph 3.12).

Exhibit 3.1 Principal organizations involved in national security program delivery, at the time of our audit[*] (continued)

Organizations	Program delivery
Financial Transactions and Reports Analysis Centre of Canada	• receives, collects, and analyzes transaction reports, provided by financial institutions, financial intermediaries, the Canada Customs and Revenue Agency, and others • discloses relevant information to law enforcement agencies, where appropriate • *Anti-terrorism Act* required disclosure of information to CSIS where there are reasonable grounds to suspect it is relevant to a threat to the security of Canada
Citizenship and Immigration Canada	• ensures immigrants and visitors do not represent a risk • deals with people-smuggling, organized crime, terrorism, war crimes, and crimes against humanity • protects Canada as a border security agency
Canada Customs and Revenue Agency	• enforces border, tax, and trade laws and regulations • protects Canada as a border security agency • responsible for helping fulfill Canada's obligation regarding illegal export of nuclear, chemical and biological weapons or compounds
Canadian Food Inspection Agency	• delivers all federal food inspection, animal health, and plant protection measures • protects Canada as a border security agency • responds to biological outbreaks of pests and diseases in plants and animals
Transport Canada	• sets and enforces security standards for air, land, and water transportation systems • evaluates information from the security and intelligence community • directs the transportation industry to take appropriate action to deal with threats • assists emergency response personnel in handling dangerous goods emergencies • responsible for overall transportation security policy and regulations but relies on others, including marine and airport authorities, to ensure transportation system is secure
Canadian Air Transport Security Authority	• screens air transport passengers and their belongings prior to boarding • screens checked baggage • provides on-board security for selected flights under a contract with the RCMP • provides federal financial support to local airport operators for airport policing related to aviation security
Fisheries and Oceans Canada	
Canadian Coast Guard	• conducts dual-use maritime surveillance to enforce fishing regulations and to support other security operations • provides control of vessel traffic

[*] On 12 December 2003, the Prime Minister announced significant changes to these organizations (see paragraph 3.12).

Exhibit 3.1 Principal organizations involved in national security program delivery, at the time of our audit* (continued)

Organizations	Program delivery
Health Canada	• operates Centre for Emergency Preparedness and Response, which co-ordinates public health security in Canada • lead department on bio-terrorism, develops and maintains emergency response plans • manages the Global Public Health Intelligence Network, which identifies disease outbreaks around the world • manages the National Emergency Services Stockpile system, which includes pharmaceuticals necessary to treat people exposed to biological agents • maintains equipment and supplies for 165 "field hospitals" with 200 beds each • operates the National Microbiology Lab, Canada's first Level 4 lab • lead department for the Federal Nuclear Emergency Plan
Natural Resources Canada	• regulates the security of energy pipelines through the National Energy Board, and explosives, nuclear energy, and materials through the Canadian Nuclear Safety Commission • complies with its security regime for nuclear facilities and other nuclear activities including armed response at power stations against penetration

*On 12 December 2003, the Prime Minister announced significant changes to these organizations (see paragraph 3.12).

Source: *The Canadian Security and Intelligence Community*, Government of Canada, 2001, and other information from departments and agencies.

before they are considered by ministers. The Deputy Clerk, Counsel and Security and Intelligence Co-ordinator chairs the ICSI Executive Subcommittee composed of deputy ministers of the core intelligence agencies and the Department of Justice. (Deputy ministers would also meet before each meeting of the Ad Hoc Cabinet Committee on Public Security and Anti-Terrorism.) Finally, an Intelligence Policy Group of officials at the assistant deputy minister rank is chaired by the Assistant Secretary of the Security and Intelligence Secretariat, Privy Council Office. These committees have been left in place.

3.18 Solicitor General Canada was responsible for maintaining the National Counter-Terrorism Plan, which outlines roles and responsibilities for managing the response to incidents of terrorism. The Senior Assistant Deputy Solicitor General chaired the Assistant Deputy Minister Committee on Public Safety, which shared many members with the Intelligence Policy Group. The Committee on Public Safety provided a co-ordination and discussion forum for policy and priority setting in law enforcement and public safety. Solicitor General Canada, with the participation of the Treasury Board Secretariat, is leading an initiative to improve information sharing on public safety and security. The department has been renamed Public Safety and Emergency Preparedness Canada and expanded to include border services and emergency preparedness.

3.19 **New funding.** During October 2001, the government approved several major new allocations of funds, including

- $30 million annually to provide immediate, permanent staff increases to the Canada Customs and Revenue Agency, Citizenship and Immigration Canada, the RCMP, and Transport Canada;
- $250 million for immediate security initiatives—largely capital and equipment—to 15 departments and agencies;
- $71.5 million in urgent funding to offset unforeseen costs such as overtime for Customs and the RCMP; and
- $160 million to compensate Canadian air carriers and specialty operators for losses resulting from the closure of Canadian air space following the September 11 attacks.

3.20 Except for the funds to compensate air carriers, these amounts were part of the $7.7 billion announced in the December 2001 Budget as new spending over 2001–02 and the following five years for enhanced security, emergency preparedness, and improving border infrastructure. The Budget was designed to keep Canada safe, keep terrorists out, and keep Canada's border open. It announced $6.5 billion for security, including the creation of a new air security authority, additional funding for intelligence and policing, and funding for Canada's military; and more than $1.2 billion for initiatives designed to make Canada's border more secure, open, and efficient.

3.21 The Budget included major investments to

- equip and deploy more intelligence and front-line investigative personnel, improve co-ordination among agencies, and boost marine security ($1.6 billion);
- improve screening of immigrants, refugee claimants, and visitors (including detention and removal), speed up the determination of refugee claims, and introduce new fraud-resistant Permanent Resident Cards ($1 billion);
- improve the protection of critical infrastructure and emergency preparedness and response; and expand the military's anti-terrorism capacity ($1.6 billion);
- create a new air security organization, place armed plainclothes police officers on Canadian aircraft, purchase explosive-detection equipment, and enhance air transportation policing ($2.2 billion); and
- enhance border security and improve the infrastructure that supports major border crossings to ensure the legitimate flow of goods and people ($1.2 billion).

Focus of the audit

3.22 This chapter focusses on two overarching themes: the overall management of the Public Security and Anti-Terrorism initiative; and the co-ordination of intelligence among departments and agencies and their ability to provide adequate information to enforcement personnel.

It examines several specific issues—the interoperability of security and intelligence information systems and the sharing of information, fingerprint identification, the use of watch lists for border control, and the security clearance of airport workers requiring passes to restricted areas.

3.23 We reported on the level of independent review of security and intelligence agencies in an audit observation included in the Auditor General's November 2003 Report, Chapter 10.

3.24 Further, we plan to conduct an audit in the future that will focus on air travel security, elements of marine security, and consequence management.

3.25 More details on the objectives, scope, approach, and criteria for the present audit are included at the end of the chapter under **About the Audit**.

Observations and Recommendations

Planning and control of the initiative

Management of the security initiative and review of departmental proposals

3.26 The Ad Hoc Cabinet Committee on Public Security and Anti-Terrorism oversaw the plan for "Enhancing Security for Canadians," a $7.7 billion component of the December 2001 federal Budget. The Committee asked deputy ministers of 17 departments and agencies to submit proposals on how they could support five broad objectives for funding decisions:

- keep terrorists out of Canada;
- deter, prevent, detect, and prosecute and/or remove terrorists;
- facilitate Canada–U.S. relations;
- support international initiatives (such as the UN, NATO, NORAD); and
- protect our infrastructure and support emergency planning.

3.27 This process was unusual in that the Privy Council Office took the lead, with support from the Treasury Board Secretariat and Finance Canada, to identify specific security measures in response to September 11. A three-agency committee (assistant deputy ministers from the Privy Council Office, Finance Canada, and the Treasury Board Secretariat, chaired by the Privy Council Office) reviewed the spending plans submitted by departments before making recommendations for inclusion in the Budget submission. Officials in departments told us the Privy Council Office had warned that it would be wary of "opportunism." Unless they were considered justified by the change in circumstances, certain items were ruled ineligible—such as reversals of Program Review cuts, unfunded Cabinet submissions, and measures to address the rust-out of equipment. There was an unwritten policy to apply the "user pay" principle wherever possible. Our examination of the process was limited primarily to interviews, as there were no formal minutes of discussions or recommendations and few documents recording discussions of proposals. Departments said they had found the review process rigorous and sometimes intimidating.

3.28 Many departments already had long-range plans prepared that encompassed the desired enhancements; the December 2001 Budget provided an opportunity to implement and expand those plans. Examples are the Customs "Action Plan 2000–2004" and Citizenship and Immigration Canada's "Permanent Resident Card" project.

3.29 Though the committee had recommended funds for allocation to departments based on their proposals, access to the funds was not automatic after the Budget was passed. Departments and agencies had to submit proposals for the Treasury Board's approval before they could obtain access to the funds.

3.30 Some proposals were for substantially higher amounts initially than the amounts that were finally approved. Examples include proposals by Citizenship and Immigration Canada and the RCMP, whose final allocations were only about a third of their original requests.

3.31 For the handful of projects that cut across a number of departmental lines, lead departments were identified to consolidate departments' separate proposals into one submission to the Treasury Board. For example, Transport Canada co-ordinated a combined submission on marine security; National Defence led an initiative to improve the response to chemical, biological, radiological, and nuclear emergencies.

3.32 The lead departments were responsible for co-ordinating discussion among the supporting departments and, after reaching consensus, preparing a consolidated submission to the Treasury Board. In one case, the Office of Critical Infrastructure Protection and Emergency Preparedness allocated funds to sub-projects in the supporting departments.

Most items selected for funding were directly connected to Budget objectives

3.33 We looked at the projects funded by the Public Security and Anti-Terrorism (PSAT) initiative and compared them with the stated objectives used in the review performed by the Privy Council Office, the Treasury Board Secretariat, and Finance Canada. The initiative's overall purposes as announced in the 2001 Budget were to keep Canadians safe, keep terrorists out, and keep the borders open. We found that the vast majority of items put forward by departments and reviewed by central agencies showed a direct connection to the stated objectives.

3.34 In the Budget section "Enhancing Security for Canadians," a total of $510 million was allocated to National Defence to support Canada's military, including $210 million to fund Canada's international military campaign against terrorism. The remaining $300 million was allocated to defence activities other than anti-terrorism initiatives, including $69 million to develop a Joint Strike Fighter, $14.5 million to develop vaccines, and $2 million to support the cadet program.

3.35 We found no evidence that officials of the Privy Council Office, Finance Canada, and the Treasury Board Secretariat had based their review of departmental proposals on a national threat and risk assessment. A framework based on such an assessment can help ensure that projects are given the appropriate priority, taking into account alternative uses of the funds and potential levels of risk.

3.36 Other projects appeared designed to maintain the government's existing public safety and policing programs, not to respond directly to the increased need for security after September 11. For example:

- The RCMP was allocated $45 million to replace an outdated occurrence management system. This is the system police use to record and store information on the bulk of their actions and investigations. After an earlier failed attempt to replace its existing system, the RCMP received approval under the initiative to acquire and implement a replacement. Funding for most of the new system's expected costs was allocated in the 2001 Budget.
- Of the $250 million in emergency funding, the Canada Public Safety Information Network was allocated $3.75 million, with an additional $4.75 million annually beginning in 2002–03. This network, managed by Solicitor General Canada, comprises many initiatives designed to improve information sharing throughout the justice system by linking criminal justice agencies with other agencies across the country, leading to increased public safety.
- Public Security and Anti-Terrorism funds were allocated to the Solicitor General to combat organized crime and the illegal drug trade in First Nations communities, including the cultivation of marijuana. This project was allocated $300,000 in 2001–02 and $1.5 million annually in ongoing funding beginning in 2002–03.

3.37 At the same time, certain proposed projects that appeared directly related to the Budget objectives were not funded fully. These included marine security and the RCMP's Real Time Identification system. We were told by officials that certain projects had not been developed well enough to be considered for funding at the time of the Budget. Marine security was addressed after the original Budget allocations, but the Real Time Identification system has not yet been funded. We could not look further at these decisions because the review process followed by Finance Canada, the Treasury Board Secretariat, and the Privy Council Office was not fully documented.

3.38 Certain other projects fall into a grey area. While they show a vague link to combatting terrorism and supporting the objectives of the Budget, these are not their main activities. For example:

- The RCMP was allocated over $5 million to replace an outdated laboratory information management system that tracks laboratory casework.
- The concept of Integrated Border Enforcement Teams (IBETs) predates the Budget, but their implementation was accelerated as a result of increased funding. The teams are designed to protect the Canadian/U.S. border at places other than ports of entry. The teams share intelligence and investigate and interdict persons and organizations that pose a threat to national security or are suspected of criminal activity. Teams

include representatives of Canadian and U.S. police and border enforcement agencies. While the vast majority of their work focusses on contraband and illegal immigrants, their investigations may provide valuable intelligence and develop into a national security investigation.

Funds from the initiative are subject to additional controls

3.39 **Restrictions on reallocation within departments.** When increased resources are approved for departments by the Treasury Board, they are most often combined with other departmental resources and are subject to the standard policies and regulations that govern spending by departments. Departments and agencies are free to reallocate their resources among programs as their needs and priorities change. However, they were not to reallocate PSAT funds for other purposes without notifying the Treasury Board and assuring it that their PSAT activities would not be affected. In certain cases, access to PSAT funds was further restricted by separating PSAT expenditures from other departmental transactions.

3.40 In most cases, departments accepted the allocation of funds as provided. In other cases, departments subsequently provided further information. For example, marine security, a horizontal project involving seven departments and agencies, was initially allocated $60 million in the 2001 Budget. After approximately $25 million of this amount was allocated to specific projects, the departments provided threat assessments that were more detailed, and the allocation was increased in January 2003 by $172.5 million to a total of $197.5 million.

3.41 Citizenship and Immigration Canada believed that reallocating the funds it had received would provide better results toward the Public Security and Anti-Terrorism objectives. It presented an alternative allocation among its projects, which the Treasury Board approved in August 2002. The emphasis was on building an intelligence capacity and improving screening to better identify and remove security risks. This is in contrast to the RCMP, who did not press for funding of the Real Time Identification system even though it underpinned the success of other projects. This is discussed in detail later in the chapter.

3.42 **Requirement to report on PSAT results.** In addition to restricting the use of Public Security and Anti-Terrorism funds to projects related to the initiative's objectives, the Treasury Board imposed a framework on departments and agencies for reporting on and evaluating their project results. This was the first attempt we had noted by central agencies to monitor the spending and results of an initiative across departmental and agency lines. We were told that this reporting requirement would not only serve to monitor progress but also provide a means for the Treasury Board to reallocate funds from certain projects to others with higher priority.

3.43 The first annual reports were due on 30 September 2003. The deadline was missed by most departments although a large number subsequently filed their reports. Therefore, it is too early to determine whether this approach to monitoring results will work. The documents that we did receive varied widely in the amount of detail on actions taken and results achieved. The

Treasury Board Secretariat needs to improve this process as a basis for central direction and better accountability to Cabinet and parliamentary committees.

3.44 It is not clear that the reporting framework will provide the information needed to oversee the initiative. Much of the funding was allocated not to establish new programs but to increase the capacity of existing programs. Consequently, while departments and agencies can estimate the amounts they have spent, it will be difficult to separate the results of the initiative's activities from those of ongoing departmental programs.

3.45 The 2003 Budget announced that the Treasury Board Secretariat would lead a series of reviews of departmental and horizontal programs. The government chose Public Security and Anti-Terrorism as one of the horizontal reviews, currently under way.

3.46 **Recommendation.** The Treasury Board Secretariat should ensure that departments and agencies with projects funded under the Public Security and Anti-Terrorism initiative complete their annual reports and detail the specific results of their projects to the appropriate committees of Cabinet and Parliament.

Treasury Board Secretariat's response. Agreed. The majority of departments and agencies have met the requirement to report on their Public Security and Anti-Terrorism initiatives for the previous year's activities, and for future years. The Secretariat is analyzing the information and will be reporting to the Treasury Board on the results. As well, the Secretariat intends to provide departments and agencies with direction by May 2004 on reporting requirements to Parliament.

Management of security intelligence

3.47 Intelligence is a product of the collection, evaluation, analysis, integration, and interpretation of all available information. Security intelligence is used to warn the government about activities that may threaten Canada's security. It is one of the most effective tools available for enforcement programs and border protection, both of which are key priorities of the government's Public Security and Anti-Terrorism initiative. Intelligence information is also needed so limited resources can be focussed selectively and precisely on the greatest threats.

The Canadian Security Intelligence Service (CSIS) National Headquarters. CSIS, along with the other organizations mentioned in this chapter, contributes to Canada's security.

Gaps in management hinder progress

3.48 The importance of intelligence in the fight against terrorism cannot be overstated. Co-ordinating the efforts of the agencies involved is acknowledged as critical to their overall effectiveness. After September 11, many departments recognized that their intelligence function needed strengthening. This was especially the case for Immigration, which created a new intelligence branch and, in March 2002, initiated a major reorganization of its intelligence function.

3.49 At the time of our audit, overall direction came from five high-level government committees that co-ordinate activities within the intelligence community. However, committees co-ordinated the activities of autonomous agencies only when there was consensus. When agencies could not reach consensus or discussions dragged on too long, they needed direction from an executive authority. Our examination showed that opportunities exist to improve co-operation and integration; to resolve disputes among organizations; and to learn from past events.

3.50 We believe that executive authority and direction based on and derived from an accountability framework are key to addressing these issues.

Better co-operation and integration are essential

3.51 The challenges of responding to threats of terrorism have made it clear that co-operation and integration are important tools. The government appears to be moving in the right direction, with efforts to more closely co-ordinate the collection of intelligence information and to encourage the exchange of information among analysts.

3.52 We expected to see the intelligence community co-operating to produce and disseminate intelligence reports efficiently. We also expected to see formal mechanisms established and controlled to co-ordinate the activities of the community, particularly analysis and distribution of intelligence.

3.53 Intelligence priorities of individual agencies are collected by the Privy Council Office, which analyzes them and draws common themes that are then presented to ministers for their endorsement at the annual Meeting of Ministers on Security and Intelligence. As these deliberations are a category of Cabinet confidences to which we do not have access, we were unable to assess this process.

3.54 **Strategic intelligence.** Strategic intelligence is based on the in-depth analysis of a threat and is a mix of open and classified material. Its purpose can be to inform policy makers or to provide background to investigators, analysts, and enforcement officials. Two principal groups produce strategic reports: the Intelligence Assessment Secretariat in the Privy Council Office and the Research, Analysis and Production Branch in the Canadian Security Intelligence Service. We were told that the Intelligence Assessment Secretariat focusses on international intelligence while the Research, Analysis and Production Branch focusses on specific threats to Canada. Users of these reports told us they had received the reports in a timely manner and in most cases had found them useful.

3.55 However, in some cases the distinction between the two areas of focus is not easy to discern, based on the similarities we saw in a number of reports from both organizations. The Privy Council Office told us that similar reports can help in ensuring that different perspectives and viewpoints inform policy making.

3.56 **Tactical intelligence.** Tactical intelligence is more urgent, warning of an imminent threat or a potentially illegal act. When intelligence agencies learn of an imminent threat to a specific person or event, they can alert enforcement agencies.

3.57 We expected to see that tactical reports or alerts reached enforcement staff promptly, and in most cases we found this to be so. However, we found that the communication of alerts can rely on personal contacts and informal networks. In one case, an alert to a potential threat was sent using the government's top secret messaging system but was addressed incorrectly. After waiting a month for a response, the sending agency followed up and found that the message had not been received. Fortunately, the alert turned out to be a false alarm.

3.58 In another case, an alert from an ally did not reach the departmental intelligence unit it was intended for because the Canadian agency that initially received it had sent it to an emergency centre, which failed to circulate it.

3.59 We also noted that the Office of Critical Infrastructure Protection and Emergency Preparedness has only limited access to the government's top secret messaging system. For urgent alerts it depends on the telephone and facsimile transmission.

3.60 **New efforts at integrating activities.** In response to the attacks of September 11, agencies in the security and intelligence community recognized the importance of integrating their activities. Information on known or suspected terrorists and on potential threats, vulnerabilities, and previous events exists in many forms and in many places. Assembling this information is the challenge facing the community.

3.61 We noted a number of examples that illustrate the need for central co-ordination. The RCMP's projects under the Public Security and Anti-Terrorism initiative included the creation of Integrated Border Enforcement Teams (IBETs) and the Integrated National Security Enforcement Teams (INSETs). Each incorporates members of other agencies and in some cases other levels of government and the United States. The concept is recognized as a good one, and the RCMP's annual report on PSAT funding has noted some successes. However, we noted that not all of the intelligence agencies participate fully in these integrated teams. Notable is the lack of full participation in the INSETs by Citizenship and Immigration Canada and its lack of members on the IBETs. Immigration officials told us that they support the IBETs initiative but decided against full participation at the present time as, in their view, the primary focus of IBETs is on drugs and contraband.

3.62 In early 2003, the Canadian Security Intelligence Service created the Integrated National Security Assessment Centre (INSAC) and outlined its purpose in a framework document. The Service envisioned a centre that would use intelligence from many sources to produce timely analyses and assessments of threats to Canada and would distribute these reports to those with national security or public safety responsibilities. It invited the following organizations to send a representative:

- Canada Customs and Revenue Agency
- Communications Security Establishment
- National Defence
- Office of Critical Infrastructure Protection and Emergency Preparedness
- RCMP
- Transport Canada
- Department of Foreign Affairs and International Trade
- Citizenship and Immigration Canada
- Solicitor General Canada
- Privy Council Office

The latter four organizations have not yet provided a representative. Foreign Affairs said that its resources should more properly address the threat to its personnel and assets abroad and that increasingly scarce resources from a 'foreign ministry' should not be devoted to matters that are better left to domestic agencies. Immigration told us it supports the concept and attributes its absence to the lack of permanent funding available for that purpose. Solicitor General Canada said that although it has not assigned a specific representative, its officials are fully engaged in all functions and work initiated by the Centre. The Privy Council Office told us that it has no intelligence collection mandate but is actively involved on a daily basis in the processing of information produced by INSAC.

3.63 Documents we reviewed show that the Canadian Security Intelligence Service created INSAC because it recognized the importance of sharing information. The concept of establishing an integrated assessment centre was endorsed by the Intelligence Policy Group. However, at the time of our audit INSAC still did not have a mandate that had been agreed to formally by all the parties. We also note that it will be less effective if four organizations in the intelligence community fail to participate fully.

3.64 While integrated units represent an improvement, in each case they were initiated by a single agency; we are concerned that participation by other departments and agencies is discretionary. We are also concerned that without an accepted framework to guide their development, such groups could proliferate and lead to duplication.

3.65 **Resolving issues among organizations.** We found cases where mandate or co-operation issues among organizations have remained unresolved for a considerable time. Specifically, we found the following:

- The potential for the activities of the RCMP and the Canadian Security Intelligence Service to overlap has increased since the *Anti-terrorism Act* was passed. Both organizations have undertaken new ways of working together, through INSETs and mutual secondments and collaboration in the scientific and technical fields. Notwithstanding that their working relationship is critical and they see it as progressing well, their memorandum of understanding covering joint work and co-operation has not been updated to reflect their revised responsibilities.
- In another case, we noted an unresolved issue between two organizations involving the use of intelligence in an investigation.

3.66 In our opinion, the most significant issue still unresolved is Customs officials' lack of access at the front line to information on lost and stolen passports (discussed in greater detail later in this chapter).

3.67 We noted that privacy concerns were often cited as the reasons why agencies could not exchange information. However, officials were not able to show us any legal opinions, specific references to legislation, or judgments as a basis for that position.

3.68 **Recommendation.** The National Security Advisor should consider the following when developing a planned integrated policy framework:

- a common understanding of domestic security;
- defined roles, responsibilities, and accountabilities; and
- clear goals and objectives based on assessments of risks, threats, and vulnerabilities.

Privy Council Office's response. Agreed.

Intelligence lessons learned from critical incidents are incomplete

3.69 It is unreasonable to expect that the government can gather sufficient intelligence to protect Canada from all attacks. What is reasonable to expect is that after any significant incident, an organization will analyze how it responded, identify the lessons it learned, and apply those lessons in the future.

3.70 **Learning from Ressam.** On 14 December 1999 a Montreal resident, Ahmed Ressam, was caught attempting to smuggle explosives into the United States from Canada. The Assistant Deputy Minister Committee on Public Safety commissioned a lessons-learned study that looked at operational deficiencies in the handling of the case and at vulnerabilities in the system. However, the Committee had no authority to direct departments to correct the problems or deficiencies that the study identified.

3.71 The lessons-learned report (30 August 2001) noted that a number of the identified problems had been fixed but that several significant issues remained unresolved. The report was based on separate lessons-learned reports submitted by individual departments and agencies. However, some agencies had not produced reports. For example, we found that while the Passport Office was significantly involved in the Ressam affair, it did not conduct a lessons-learned analysis.

3.72 **Post-September-11 analysis.** We expected also to see a lessons-learned study that assessed how the Government of Canada had responded to the attacks in the United States. We found a wide variety of reports. In some cases, extensive analyses were carried out but never endorsed by senior management; lack of support by senior management undermines any effort to implement change. In other cases we were given basic reports that appeared to be summaries but that provided no detailed analysis (Exhibit 3.2).

3.73 The Assistant Deputy Minister Committee on Public Safety produced an overall report that included a large section on assessments by provincial and territorial governments. The Committee produced an action plan and a status report in fall 2002. However, we found no reporting of progress made against the recommendations since that date.

Exhibit 3.2 Assessment of lessons-learned reports

Department or agency	Lessons-learned report		Executive approval	Action plan	Status reports
	Summary	Internal report			
Privy Council Office	✓				
Solicitor General Canada	✓	✓		✓	✓
Canadian Security Intelligence Service	✓				
Royal Canadian Mounted Police	✓			✓	
Office of Critical Infrastructure Protection and Emergency Preparedness		✓		✓	
Citizenship and Immigration Canada	✓			✓	
National Defence		✓	✓	✓	
Transport Canada		✓		✓	
Canada Customs and Revenue Agency		✓		✓	
Communications Security Establishment	✓			✓	

3.74 The Interdepartmental Committee on Security and Intelligence proposed that heads of agencies meet with the Clerk of the Privy Council to provide a high-level perspective on the government's response to September 11. We noted that a four-page discussion paper prepared for that meeting was the only government-wide post-mortem analysis conducted. The heads of the RCMP, the Canadian Security Intelligence Service, and Finance Canada were not present at the dinner meeting held to discuss the paper. No record of the discussion was kept and no follow-up or action plan resulted.

3.75 We were told that a presentation was made to the annual Meeting of Ministers on Security and Intelligence but that no minutes were kept and no action plan was produced.

3.76 **Recommendation.** The National Security Advisor, with Public Safety and Emergency Preparedness Canada, should carry out a government-wide lessons-learned analysis after any significant security incident. Such an analysis should include an action plan that addresses the deficiencies identified and regular follow-up to assess progress.

Privy Council Office's response. Agreed.

Public Safety and Emergency Preparedness Canada's response. The Counter-Terrorism Operational Readiness section of the National Security Directorate has an informal lessons-learned process in place, which is incorporated in the development of scenario-based exercises, seminars, and workshops. Additionally, Public Safety and Emergency Preparedness Canada is amending its national response structure to capture lessons learned from operations and to incorporate these lessons into operational procedures. The formalized version of this lessons-learned process will address deficiencies and conduct regular progress assessments.

Interoperability and information sharing

Problems with the interoperability of information systems

3.77 **A priority after September 11.** The government identified the interoperability of security information systems and the sharing of information as high priorities after September 11. The goal of interoperability was to make sure that those who needed information for their operations could get it and use it. The federal government knew that there were information "stovepipes" among federal departments and agencies and other levels of government. These barriers could prevent the timely recognition of threats to Canada and delay its response to terrorists or other emergencies, or make its response less effective.

Dimensions of interoperability

Technical—Systems applications transferring information

Semantic—Standardization of terminology and definitions

Human—The cultural willingness of organizations to share information

Inter-community—Pursuing partnerships and common solutions across departmental or jurisdictional barriers

Legal—The legal framework that allows sharing of information

Source: Interoperability Working Group and Treasury Board Secretariat

3.78 **Problems in this area contribute to other deficiencies noted.** Elsewhere in this chapter we discuss problems that could be defined as a lack of interoperability or of information sharing:

- Watch lists require the timely sharing and transfer of information between those who collect the information and the Customs officers on the front line who use it in protecting Canada's borders.
- Information on lost and stolen passports needs to be available to officials on the front line.

- The increased reliance on intelligence requires a more effective and efficient means of sharing information among intelligence agencies.
- Officials screening people who work in secure areas of airports require more complete information from police to make informed decisions.

3.79 **Assistant deputy minister working group problems.** In October 2001 the government formed the Interoperability Working Group, comprising assistant deputy ministers of departments and agencies with security and intelligence responsibilities. The group's objectives were to identify opportunities to enhance public safety, establish a list of "quick hits" (fixes) and medium-term initiatives to be pursued immediately, and propose a long-term vision and strategy to harmonize processes and improve information sharing.

3.80 Departments and agencies began to work on some of the "quick hits" immediately after the working group identified its list in February 2002. The working group made a presentation to the Ad Hoc Cabinet Committee on Public Security and Anti-Terrorism in June 2002. The Chair of the working group approved an interim report in September 2002, but it was never submitted to Cabinet.

3.81 The working group ceased to exist after June 2002, and we found no evidence to show that central direction had reassigned its responsibilities elsewhere. In November 2003, Solicitor General Canada was asked by the government to lead a program development initiative to improve the sharing of information for public safety and security, with the participation of the Treasury Board Secretariat. Given the priority of the issues involved and the potential impact on public safety and the security of Canadians, this delay points to a lack of central direction.

3.82 Solicitor General Canada led a study of how information was shared at Pearson International Airport. The study found that information sharing often relied more on established personal relationships than on operational procedures or integrated electronic information systems. In some cases, guidelines restricted the sharing of information among departments. There were duplicate entries and duplicate searches among different departmental databases. There was a lack of co-ordination among agencies, which could hamper investigations. There were gaps in the information available for determining whether airport employees should be granted or should retain their security clearance. We made similar observations in the course of our audit.

3.83 **Slow progress on "quick hits."** We found that progress on the quick hits identified by the Interoperability Working Group has not been sustained. In fact, in some areas where progress was reported it has since deteriorated. Only three projects have been completed successfully—for example, the provision of information on lost and stolen licence plates to our land border ports of entry; two have made doubtful progress; and five have made no progress since September 2002—for example, front-line officers at airports still do not receive passport information.

3.84 **Recommendation.** Departments responsible for "quick hits" and other issues related to interoperability and information sharing should speed up efforts to resolve identified problems. The Treasury Board Secretariat and Public Safety and Emergency Preparedness Canada should monitor those efforts.

Treasury Board Secretariat's response. The Secretariat agrees that it will ensure the monitoring of these initiatives for sustained progress and expected results.

Public Safety and Emergency Preparedness Canada's response. The Department agrees with this recommendation and currently monitors the effective and appropriate implementation of the "quick hits" and other desired connectivities, as identified by post 9/11 working groups and others.

The "Public Safety and Security Information Sharing and Interoperability" project will consolidate these "hits" with other known gaps and ensure that public safety and security connectivities are prioritized and pursued as appropriate. Public Safety and Emergency Preparedness Canada and the Treasury Board Secretariat will work collaboratively to ensure that departments and agencies who are implementing these new connections receive support in co-ordinating their work with other agencies, in addressing any emerging Government of Canada public policy issues; and in obtaining any needed funding.

Other issues not addressed by the Interoperability Working Group

3.85 One initiative with significant interoperability requirements is Advance Passenger Information and the Passenger Name Record (API/PNR). Legislation passed in fall 2001 requires airlines to provide the government with API/PNR information in order that Customs and Immigration staff can identify and assess the risks presented by travellers before they arrive in Canada. Airlines collect API data when passengers check in; PNR is drawn from airline flight reservations systems and includes itinerary and method of payment. The effectiveness of this initiative depends on the databases of a large number of organizations other than the airlines, including Customs, Immigration, Taxation, RCMP, CSIS, and agencies in the United States.

3.86 In October 2002, government departments began to collect API data. There were problems in obtaining data from one major airline, but these have been resolved. Progress is being made on PNR but it is slow, due in part to technical issues that must be overcome with each airline. Another obstacle is that airlines in the European Union have been prevented from providing data due to privacy concerns. In partnership with the United States, Canada has been developing an automatic evaluation of risks posed by arriving passengers. The two countries plan to share information on passengers whose risk scores exceed a pre-determined threshold.

3.87 Another significant weakness is the absence of a government-wide system that would allow communication at the "secret" level among departments and agencies. A project undertaken by one agency was abandoned when the proposed methodology was found to be vulnerable to attack. In November 2003, the government undertook to renew the development of a communications system at the secret level to complement the existing system for communication at the top-secret level.

3.88 **Recommendation.** Public Safety and Emergency Preparedness Canada and the National Security Advisor, with the assistance of the Treasury Board Secretariat, should co-ordinate and oversee the implementation of a government-wide communications system at the secret level.

Public Safety and Emergency Preparedness Canada's response. The Department recognizes and supports the need for a government-wide communications system at the secret level and continues to support the planning and pursuit of related funding strategies for such an initiative, which will form part of the "Public Safety and Security Information Sharing and Interoperability" project.

Privy Council Office's response. Agreed that there should be a government-wide capacity to share secret information.

Treasury Board Secretariat's response. The Secretariat will assist Public Safety and Emergency Preparedness Canada and the National Security Advisor in ensuring that the communications system adheres to government-wide security and privacy policies.

Priorities not yet identified

3.89 At the time of this writing, the government had just brought forward a proposal to develop a plan for the sharing of public safety and security information. This plan will not deal with specific issues or individual information systems but will identify priorities and provide a framework to develop solutions. Developing such a plan was part of the longer-term vision of the Interoperability Working Group. Over the next two years, the plan will involve all departments and agencies with police, enforcement, legal, and intelligence responsibilities in the criminal justice and national security communities. Government officials recognize that this work has been delayed too long.

3.90 The scope of the plan is very broad—it calls for examining the relationships among agencies and their hundreds of information systems, repositories of data, and the processes they support. It will not absorb or direct the ongoing development and implementation of projects now under way. However, it will attempt to link these projects, some of which involve development costs in the hundreds of millions of dollars, to allow for better sharing of information.

3.91 The planning project is led by Public Safety and Emergency Preparedness Canada (formerly Solicitor General Canada), assisted by Canada's Chief Information Officer in the Treasury Board Secretariat; it will cost more than $9 million. The Chief Information Officer will provide expertise in a large part of the project design and implementation.

3.92 **Access/privacy concerns.** To protect the privacy of individuals, many of Canada's laws prevent the sharing of information within the government.

We found that in some situations, departmental officials would not share or examine the possibility of sharing information, based on the assumption that it would contravene the principles of the *Privacy Act*. However, the *Privacy Act* accommodates the sharing of information among federal government agencies in a variety of situations, including for reasons of national security. We believe that some decisions not to share information were made without a proper examination of potential security concerns.

3.93 In some cases, those requesting information asked for access to complete information systems. While this raises a legitimate privacy concern, a simple solution could be to isolate the requested information and make it available outside the main system, still protecting the privacy of individuals.

3.94 **Recommendation.** The Privy Council Office and Public Safety and Emergency Preparedness Canada, with the assistance of the Department of Justice Canada and the Treasury Board Secretariat, should further examine and provide guidance on the sharing of information among government departments and agencies while balancing privacy concerns with national security concerns.

Privy Council Office's response. Agreed that the Privy Council Office and the Department of Public Safety and Emergency Preparedness should ensure that such guidance is provided to departments and agencies through the responsible departments, namely the Treasury Board Secretariat and Justice Canada.

Public Safety and Emergency Preparedness Canada's response. The Department is very mindful of the privacy implications of any information sharing and is developing, in partnership with other federal agencies and departments and in keeping with Treasury Board Secretariat Information Management policies, a framework for managing information under the Canada Public Safety Information Network, which respects Canadian privacy legislation and the Charter of Rights and Freedoms and enables effective information sharing in support of public safety and security.

Justice Canada's response. Agreed. We look forward to providing our expertise to government agencies to assist in enhancing our national security.

Treasury Board Secretariat's response. The Secretariat will continue to provide policy guidance in the areas of information management, privacy, and security with respect to the sharing of information among government departments and agencies.

Improving fingerprint identification

3.95 **Cornerstone of security identification programs.** Fingerprints are the fundamental biometric identifier on which criminal and security identification rests. Without fingerprints it is difficult to distinguish between persons with the same name or physical appearance, and it is extremely difficult to detect someone using a false identity. Fingerprints are used to positively identify applicants for security clearances, visas, and refugee claims. Canada has a single, national fingerprint identification system run by the RCMP.

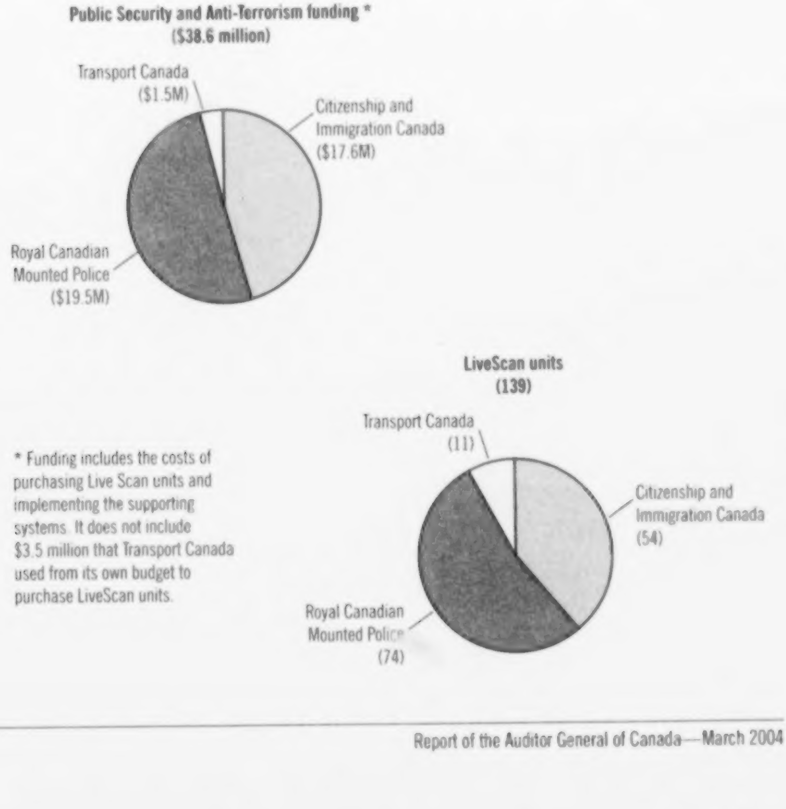
3.96 Currently the fingerprint identification system has a fixed capacity, dependent on about 100 analysts. Training more analysts would take two years and would temporarily lower the production of experienced analysts, who would be needed to provide the training. Capacity can be significantly increased only by replacing the current analytical process with an automated one.

3.97 The Public Security and Anti-Terrorism initiative included $38.6 million to improve the collection of fingerprints by using electronic LiveScan machines that take a digitized image. The funds were allocated to Citizenship and Immigration Canada, Transport Canada, and the RCMP (Exhibit 3.3). In the case of Transport Canada, the funding was used to extend its existing automated fingerprint identification initiative.

3.98 **LiveScan was seen as a major initiative for fighting terrorism and increasing security at ports of entry.** LiveScan is an automated process for taking fingerprints, palm prints, and photographs of selected individuals. Fingerprints are transmitted electronically to the RCMP. Upon receipt, these prints are manually searched against the RCMP's national database, which contains 3.3 million sets of fingerprints including those of refugees and of criminals.

3.99 In 2001, Citizenship and Immigration Canada, Transport Canada, and the RCMP purchased LiveScan equipment to modernize their fingerprinting

Exhibit 3.3 Implementation of the LiveScan project



Public Security and Anti-Terrorism funding *
($38.6 million)

LiveScan units
(139)

* Funding includes the costs of purchasing Live Scan units and implementing the supporting systems. It does not include $3.5 million that Transport Canada used from its own budget to purchase LiveScan units.

An officer taking fingerprints using an automated LiveScan machine.

processes. Citizenship and Immigration Canada uses these machines to send prints of refugee claimants and inadmissible persons at ports of entry to the RCMP to verify their identity. Transport Canada uses them in determining whether to grant airport workers clearance to restricted areas. At Transport Canada's request, the RCMP runs the workers' fingerprints through the national database to see if they have a criminal record or are a risk to security. The Canadian Police Information Centre's database is also checked to see if the names match any active records in that system. The RCMP uses the national database to run checks on suspected criminals as well as public and private sector individuals who need a security check as a condition of employment.

3.100 **Increased demand for fingerprint services.** The Forensic Identification Services branch of the RCMP is responsible for checking fingerprints against the national database. In the last two years, the branch has faced a growing demand to do more work with the same level of resources. For example, fingerprint analysis is now required in Canada Customs' Free and Secure Trade program and British Columbia's name change legislation; there are also more requests for checks of employees working in restricted areas.

Business cases for LiveScan were inadequate

3.101 There were 139 LiveScan machines purchased with Public Security and Anti-Terrorism funding. The cost of the machines and the planned expenditures on systems and maintenance until 2006–07 total $38.6 million. Transport Canada spent an additional $3.5 million from its own budget. We reviewed each of the business cases developed for the LiveScan project by Transport Canada, Citizenship and Immigration Canada, and the RCMP.

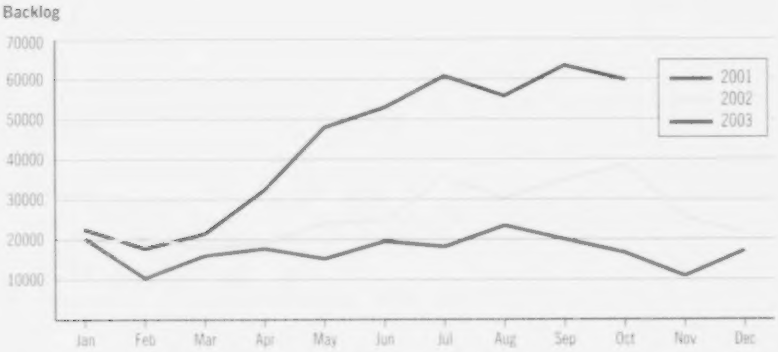
3.102 We found that the business cases developed by Citizenship and Immigration Canada and the RCMP were inadequate. They did not provide enough information on the benefits of LiveScan; nor did they include an adequate framework for risk analysis. For instance, because the benefits of LiveScan were inextricably linked to the Real Time Identification system (RTID), which was needed to complete the automated process for analyzing fingerprints, we believe the business cases should have fully explored the fact that a failure to implement RTID posed a major risk to the success of LiveScan. In addition, these two business cases did not include an adequate options analysis. We could not tell whether there were options available for fingerprinting other than the system that was chosen.

3.103 Transport Canada's business case met our criteria but based its estimate of benefits on the assumption that the RCMP would have RTID in place by the end of 2003. The RCMP did not receive the funds it would have needed to have RTID running by then. Benefits that Transport Canada estimated at $13 million have not been realized.

3.104 **LiveScan did not improve turnaround times.** Each department claimed that LiveScan would reduce turnaround times for fingerprint analysis. However, our audit found that these benefits were marginal at best.

Fingerprints submitted for analysis have been of higher quality, leading to fewer rejects and improved accuracy. Although Transport Canada has processed four times more fingerprint files per month since the introduction of LiveScan, this is due not so much to the introduction of LiveScan as to additional RCMP personnel funded by Transport Canada and assigned to clearances for access to restricted areas at airports. Moreover, with the increase in demand for fingerprint analysis there has been a corresponding increase in the backlog of work. It would take over two and a half months to clear the backlog if no new requests for analysis were received. Therefore, while the turnaround times for Transport Canada's requests have clearly improved, the requests to the RCMP from other organizations have been added to the backlog (Exhibit 3.4).

Exhibit 3.4 Backlog of fingerprints at the RCMP's Forensic Identification Services, 2001–2003



Note: An average of 20,000 fingerprints are assessed each month.

3.105 The RCMP developed a memorandum of understanding with Citizenship and Immigration Canada on turnaround times. Although the RCMP puts a high priority on processing the prints of suspected terrorists, the agreement establishes a turnaround time of six to eight weeks for most work requested by Citizenship and Immigration Canada. This is the same as the standard before LiveScan.

3.106 The RCMP provided no information to show that LiveScan had improved turnaround times in its detachments.

3.107 **Recommendation.** The RCMP should find and implement a solution to deal with its fingerprint backlog.

RCMP's response. We agree with this recommendation. Indeed, the RCMP is committed to improving service delivery and has undertaken to secure funding for a long-term solution, a major project called Real Time Identification (RTID), for the full automated processing of fingerprints. In the interim, the RCMP is addressing the backlog by hiring additional employees, although these resources need to be supplemented due to the increasing demands. Both solutions, however, require funding not presently approved.

Public Safety and Emergency Preparedness Canada's response. The Department agrees that a solution to the fingerprint backlog is needed. The "Public Safety and Security Information Sharing and Interoperability" project will address interoperability pressures, including the need for modern fingerprint capabilities at the RCMP. In the interim, policy options for dealing with the backlog will be reviewed.

LiveScan does not provide a fully automated system

3.108 LiveScan takes fingerprints and transmits them in a digital format, but an outdated manual process is still used to analyze and compare them. The RCMP told us that it had proposed a central computerized system to analyze digitized fingerprints—the Real Time Identification system (RTID)—but had not received funding for it. Officials at the Treasury Board Secretariat explained that the RCMP's business case for RTID was not sufficiently developed to justify its funding. However, LiveScan without RTID will not achieve the efficiency levels estimated in the three separate business cases for LiveScan. The RCMP continues to seek funding for RTID. If it receives the funding it will still be three to four years before the RCMP sees the benefits that RTID promises for the fingerprinting process. If it does not obtain the funding, the benefits of electronic fingerprinting will take even longer to achieve.

3.109 **Recommendation.** The RCMP and Public Safety and Emergency Preparedness Canada should give priority to implementing the Real Time Identification project.

RCMP's response. Agreed. In the wake of September 11, 2001, there was considerable public pressure to demonstrate responsiveness in a short period of time. This urgency was the context within which some decisions were not continually validated between agencies. The decision to support the deployment of LiveScan technology without supporting the critical fingerprint processing infrastructure was unfortunate. Funding needs to be allocated to this area as soon as possible.

Public Safety and Emergency Preparedness Canada's response. The Department agrees that implementation of the Real Time Identification project is a priority and continues to support the planning and pursuit of related funding strategies for this initiative, which will form part of the "Public Safety and Security Information Sharing and Interoperability" project.

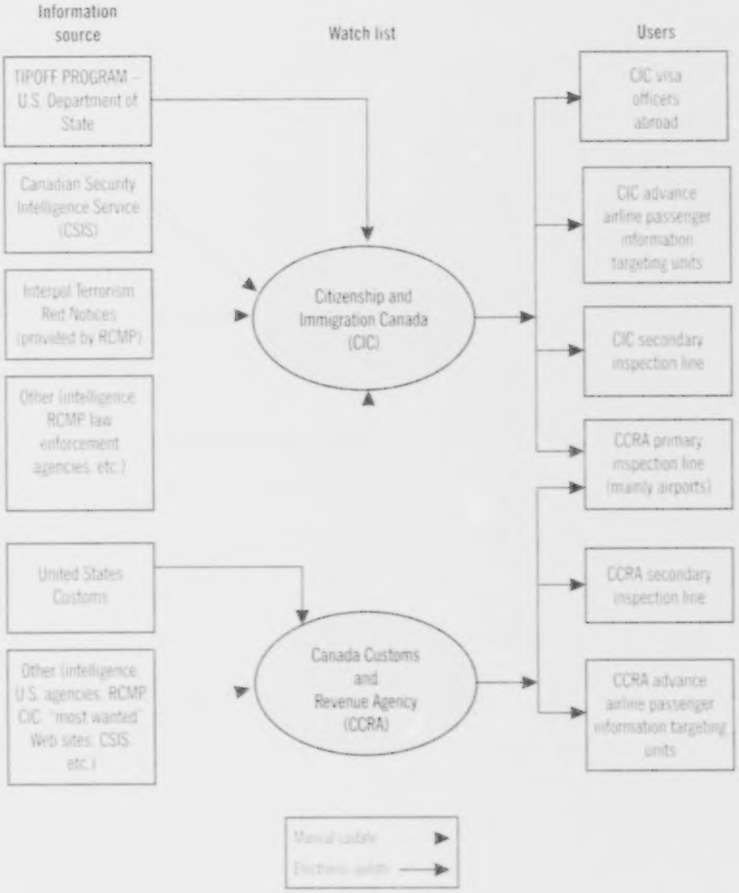
Terrorist watch lists

3.110 Watch lists play a critical role in ensuring our national security. They are a key tool in combatting terrorism by stopping terrorists before they reach Canada or by intercepting them at our ports of entry. Since September 11, the number of names on watch lists has grown dramatically. At Canada's airports, Customs officers on the primary inspection line check the names of arriving passengers against the watch lists. Watch lists are also used as an essential check in issuing visas, of which nearly 900,000 were issued in 2003.

3.111 A small number of federal departments manage watch lists under a range of mandates that collectively contribute to national security. Citizenship and Immigration Canada and the Canada Customs and Revenue Agency are the primary users of watch lists for border control. The watch lists used by Immigration and Customs officials are derived from a small number of both foreign and domestic sources. Exhibit 3.5 provides an overview.

3.112 The Canadian Security Intelligence Service provides Citizenship and Immigration Canada with "lookout" notices on persons it believes are inadmissible to Canada, including those who are believed to be a threat. These include known or suspected terrorists against whom the Service has enough information to support immigration inadmissibility proceedings as well as persons against whom it has less information but believes warrant close scrutiny.

Exhibit 3.5 Border control watch lists


Information source
Watch list
Users
TIPOFF PROGRAM – U.S. Department of State
Canadian Security Intelligence Service (CSIS)
Interpol Terrorism Red Notices (provided by RCMP)
Other (intelligence, RCMP, law enforcement agencies, etc.)
United States Customs
Other (intelligence, U.S. agencies, RCMP, CIC, "most wanted" Web sites, CSIS, etc.)
Citizenship and Immigration Canada (CIC)
Canada Customs and Revenue Agency (CCRA)
CIC visa officers abroad
CIC advance airline passenger information targeting units
CIC secondary inspection line
CCRA primary inspection line (mainly airports)
CCRA secondary inspection line
CCRA advance airline passenger information targeting units
Manual update
Electronic update

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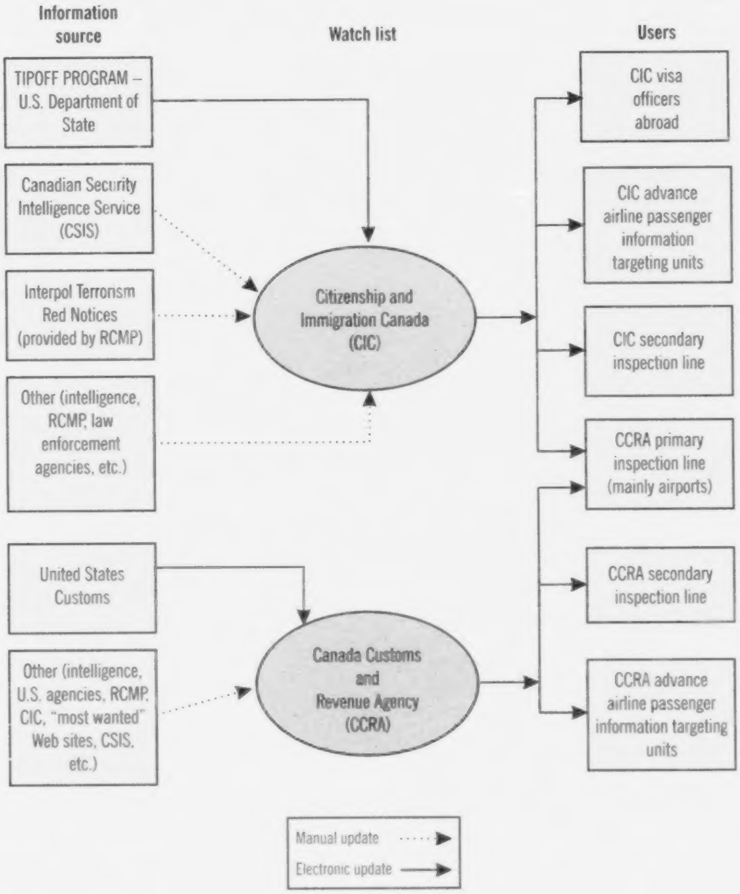
Information source
Watch list
Users
TIPOFF PROGRAM – U.S. Department of State
Canadian Security Intelligence Service (CSIS)
Interpol Terrorism Red Notices (provided by RCMP)
Other (intelligence, RCMP, law enforcement agencies, etc.)
United States Customs
Other (intelligence, U.S. agencies, RCMP, CIC, "most wanted" Web sites, CSIS, etc.)
Citizenship and Immigration Canada (CIC)
Canada Customs and Revenue Agency (CCRA)
CIC visa officers abroad
CIC advance airline passenger information targeting units
CIC secondary inspection line
CCRA primary inspection line (mainly airports)
CCRA secondary inspection line
CCRA advance airline passenger information targeting units
Manual update
Electronic update

3.113 The Canadian Security Intelligence Service uses a manual, paper-based process to transfer new lookouts, modifications, and cancellations to Citizenship and Immigration Canada.

Errors in terrorist watch lists

13
14
Canada

A traveller is screened at Customs' primary inspection line.

3.114 In our initial audit work we found significantly fewer terrorist lookouts in the Service's tracking system than in Immigration's database, so we did a detailed comparison of the two lists. We found that Immigration's records were in such disarray that we were unable to complete a full reconciliation during the course of our audit. We found

- terrorist lookouts missing,
- extensive duplication of records within Immigration's database,
- classification errors that could result in inappropriate handling of individuals entering Canada, and
- names listed that should have been removed from Immigration's database.

3.115 System and resource problems in the Canadian Security Intelligence Service can contribute to delays in putting names on watch lists. In one case, a known terrorist's name was approved for inclusion on a watch list but was not listed for over a year because the submission was lost in the Service's watch list computer system. Other listings were delayed because managers involved in the approval process were busy with other priorities. Also, some names were not reviewed regularly by the Service to determine whether they should remain on the watch lists, as it did not have a record of having placed the names on Immigration's watch list.

3.116 We also found occasional administrative delays in the Service's co-ordinating unit and inputting delays at Citizenship and Immigration Canada. These delays mean that it can take days for approved additions to watch lists and weeks for modifications before they are reflected in Immigration's database. The Canadian Security Intelligence Service and Citizenship and Immigration Canada informed us that urgent changes are given priority, and our findings generally supported that assertion.

Problems in updating watch lists

3.117 Most additions to Canada's watch lists came from the United States government's TIPOFF program. It also provided the only automated feed into our border terrorism watch lists that adds, modifies, and deletes lookouts electronically.

3.118 The TIPOFF terrorist watch list program served as a clearing house for sensitive information provided by both foreign and domestic agencies. At the time of our audit it contained about 100,000 name records of suspected terrorists, obtained mainly from the Central Intelligence Agency, the Federal Bureau of Investigation, and the National Security Agency. The size of this database has grown significantly since September 11. Reports show that the

United States has also experienced difficulty in assembling unified and comprehensive watch lists from different organizations.

3.119 At the time of our audit, Immigration's watch list contained 37,000 lookouts obtained from TIPOFF. Upon reviewing Immigration's records we found significant, sporadic breaks between updates otherwise obtained monthly from the U.S. State Department. Immigration told us that these delays were due to competing priorities, staffing problems, and certain technological issues. Specifically,

- there were no updates from the end of June 2003 to mid-October 2003. When Immigration's records were finally updated, the names of more than 8,000 suspected terrorists were added;
- there were no updates from November 2002 to May 2003. When Immigration finally updated its records, it added the names of over 5,000 suspected terrorists; and
- there were no updates from June 2001 to November 2001. When Immigration finally updated its records it added over 1,500 names. Those left off the list included two of the September 11 hijackers whom U.S. authorities had identified in August 2001.

3.120 Although the data exchange between Immigration and TIPOFF is automated, names of suspected terrorists from TIPOFF are frequently rejected by Immigration's system due to incompatible coding. Those names do not make the watch lists until Immigration staff have reported the problems to the U.S. State Department. Any corrections would be included in the next update. In our review of reports on system-generated errors, we saw names that had been rejected and not corrected.

3.121 **Interpol Red Notices.** Interpol Red Notices are used by member countries to seek the arrest and extradition of fugitives. Red Notices have been issued on some of the world's most dangerous organized crime and terrorist figures: in 1998 a Red Notice was issued on Osama Bin Laden. Interpol reported that in 2002 over 1,200 people were arrested world-wide, in part as a result of its Red Notices. In April 2001, the Canadian government began including Interpol Red Notices on Immigration's watch list to prevent international fugitives from entering Canada.

3.122 The RCMP receives Interpol Red Notices, which are then provided to Immigration for addition to its watch list using a manual, paper-based process that is slow and prone to error. We conducted a number of tests and found the following:

- Immigration's records were incomplete. We examined a representative sample of Red Notices contained in Interpol's Terrorism Watch List, a classified subset of Red Notices. Based on the results, we estimate that Immigration's watch list is missing 8 percent of the wanted terrorists.
- Of the "recent" notices posted on Interpol's publicly available Web site, 27 percent were not on Immigration's watch list.

- Of the Red Notices for 2002 that Interpol had cancelled and that the RCMP subsequently removed from its database, 53 percent had not yet been removed from Immigration's watch list.
- Delays exist between the publication of Interpol Red Notices and their entry into the RCMP database, due to mailing time and backlogs at the RCMP. We looked at a random sample of 118 Red Notices published in 2003 and entered into the police database up to mid-July, 2003 (about a third of the total number). On average, 48 days elapsed from publication to entry in the police system. At the time of our testing, the RCMP had a backlog of 162 notices to be entered in its database that were two months old, on average.

3.123 According to the RCMP, Interpol has introduced a new electronic system that a number of other countries are using and that provides Red Notice information on a timely basis. Although this system could significantly reduce the present delays, at the time of our audit the RCMP had no concrete plans to use it.

Lost and stolen Canadian passports not on border control watch lists

3.124 On average, more than 25,000 Canadian passports are reported lost or stolen each year. The RCMP believes that lost and stolen passports are a concern for our national security because of their potential use by terrorists or other criminals.

3.125 Border watch lists do not contain the list of lost and stolen Canadian passports. In April 2003, the Passport Office instituted a policy that once a passport is reported lost or stolen, it is permanently deactivated. However, the information system used on the primary inspection line cannot distinguish between active and deactivated passports.

3.126 Discussion of this issue among the Passport Office, Customs, and Immigration began in January 2003 and was ongoing at the time of this audit but had generated no solution or corrective action. We were told that privacy concerns had to be overcome before the Passport Office could share the list of lost and stolen passports with Citizenship and Immigration; then the list in the Customs primary inspection line system would be updated.

3.127 Although information on lost and stolen passports is not on our border watch lists, it is entered into an RCMP database using a manual process that is paper-based, time-consuming, and prone to error. There are long delays between the reporting of a lost or stolen passport and the entering of the information into the RCMP database. We examined a representative sample of 97 entries made in the database during the 12 months ending August 2003. About 12 percent of those entries were abnormal, taking over 243 days; the rest of the sample took 70 days, on average.

3.128 Most of the delays reflect how long it takes the Passport Office to send forms to the RCMP. Some of the more exceptional delays represent passport losses reported to Canada's missions abroad. Delays are compounded when the RCMP rejects illegible handwritten forms and sends them back to the Passport Office for correction and resubmission.

3.129 Although no backlog existed when our audit began, by the end of our audit the RCMP's data entry was one month behind and had a backlog of 4,032 forms waiting to be entered in its database on lost and stolen passports. The RCMP informed us that it is currently addressing the backlog.

3.130 The Passport Office has its own database that includes lost or stolen passports, but it is not linked or reconciled with the RCMP's. At the time of our audit about 65,000 lost or stolen passports were recorded in the Passport Office's database. After we completed our audit, the RCMP and the Passport Office informed us that they had reached an agreement in principle for the Passport Office to enter information on lost and stolen passports directly into the RCMP's database.

Outstanding warrants for serious criminal offences not all on watch lists

3.131 On 24 September 2003, the RCMP database contained about 162,000 outstanding Canada-wide arrest warrants for serious criminal offences (not including immigration warrants). There is no system that transfers information on outstanding warrants to the border watch lists; although Immigration and Customs manually check names, this is not done at the primary inspection line. This means that the automatic computer checks at the primary inspection lines and computer checks made against passenger lists in advance of international flights cannot flag persons wanted under Canada-wide warrants. Customs may enter lookouts on fugitives manually when specific information is provided by police or found during periodic scans of most-wanted lists on the Internet.

3.132 After we completed our audit, Customs informed us that it would be implementing a system that incorporates warrants contained in the RCMP database into information provided to officers on the primary inspection line. This will be provided only at airports as land ports of entry focus on licence plates rather than the names of individuals.

3.133 **Recommendation.** The RCMP, the Canadian Security Intelligence Service, the Canada Border Services Agency, and the Passport Office should improve their management and co-ordination of watch-listing efforts that collectively contribute to Canada's national security.

RCMP's response. Agreed. The RCMP is actively working with all partners to improve both the reliability and timeliness of data going to watch lists and the dissemination of the intelligence.

Canadian Security Intelligence Service's response. Agreed. The Service recognizes that the Auditor General is making overall conclusions in relation to the security and intelligence community into which our programs feed. The Service exerts rigorous control in its management of entries into the watch list, in monitoring entries in-house, and in providing quality control by examining each case against CIC's legislative criteria before processing, and will continue to do so.

Canada Border Services Agency's response. CBSA agrees to the recommendation and will continue to work with our partners to improve the management and co-ordination of watch-lists.

The CBSA (Customs and Immigration Intelligence) has recently established the National Risk Assessment Centre (NRAC) to serve as the focal point for managing and co-ordinating national and international watch lists.

A pilot project is being planned with the RCMP to have direct access to the RCMP Interpol database that will allow daily access to new Interpol notices.

Foreign Affairs and International Trade's response. Agreed. We have developed a memorandum of understanding with Citizenship and Immigration Canada (to be transferred to the Canada Border Services Agency) for the sharing of data at the Primary Inspection Line (PIL).

3.134 **Recommendation.** The RCMP, the Canadian Security Intelligence Service, the Canada Border Services Agency, and the Passport Office should improve the reliability of watch lists by enhancing quality control over the exchange of data to ensure that information is complete, accurate, and timely.

RCMP's response. Agreed. The Canadian Police Information Centre (CPIC) Advisory Committee, comprising representatives of all CPIC partners, is now considering a proposal to move to Interpol's Automated Electronic Automated Search Facility system. If approved, this will significantly increase the speed of dissemination.

Canadian Security Intelligence Service's response. Agreed. The Service remains committed to working with lead agencies on interoperability, which would improve the program from a point of view of reliability and timeliness, thus ensuring better accuracy. The Service, which is fully automated internally, is inhibited from electronically interfacing with the recipients due to their inability to receive information in that format.

Canada Border Services Agency's response. CBSA agrees to the recommendation and will continue to work with our partners to improve the reliability of watch lists.

The exchange of data is already improving, as the Passport Office list of lost and stolen passports will be available to CBSA officials at the ports of entry by the summer of 2004.

Another significant achievement to be realized in the short term relates to automated searches for outstanding warrants, which are contained in the Canadian Police Information Centre (CPIC) database. Under the API/PNR program, CBSA currently targets high-risk air passengers and checks for warrants associated with these passengers through CPIC. By spring 2005, all air passengers' names (and eventually all sea passengers') will be searched against CPIC for outstanding warrants prior to their arrival in Canada.

Additionally, a quality assurance project was put in place in September 2003 to manually review all watch lists available to front-line staff and to address exception reporting. The project will be completed by March 2004.

In the medium term (within the next three years), technological improvements will permit all watch lists (terrorism, criminal, and lost and stolen passports) to be automatically updated via an electronic link between the originating holders of information and the new Global Case Management System shared by CBSA and Citizenship and Immigration Canada.

Foreign Affairs and International Trade's response. Agreed. The transfer of responsibility from the RCMP to the Passport Office for data entry of lost and stolen passports into the Canadian Police Information Centre (CPIC) database will reduce the handling of information and the risk of duplication, and it will improve the timeliness and integrity of the data.

Security clearances for airport workers

Improving air transport security was a major objective

3.135 One of the major objectives of the 2001 Budget was to improve security at Canada's airports. According to the Budget document, "Rigorous new national standards for security in airports and on board flights are essential to protecting people. This budget will therefore provide Transport Canada with funds to strengthen its capacity to set regulations, review standards, and monitor and inspect all air security services."

3.136 The Budget allocated $2.2 billion over five years to fund improvements that included

- creating the Canadian Air Transport Security Authority to be responsible for passenger and baggage screening and contributing towards policing at airports. The RCMP is responsible for placing armed police on flights;
- hardening aircraft cockpit doors to prevent the takeover of the flight deck by hijackers; and
- tightening access to aircraft by strengthening security zones at handling facilities and on airport tarmacs.

3.137 The Budget did not specifically allocate funds to improve the security screening of airport workers with "air side" access—that is, those working in controlled-access areas of the airport where baggage and freight are handled and aircraft are serviced. If workers in secure zones are unreliable, many of the other improvements will be ineffective.

3.138 Over 110,000 workers in Canada's airports have access to the "air side." Transport Canada screens each worker to eliminate persons who are known or suspected to be involved in threats of violence against persons or property, who are known or suspected to be members of an organization involved in violence or "closely associated" with such a person, or who the Minister of Transport reasonably believes might be prone to interfering with civil aviation.

3.139 Transport Canada screens each applicant for an air side clearance by checking for

- a criminal record,
- terrorist links, and
- unreasonable indebtedness.

3.140 Transport Canada performs credit checks on its own and relies on the RCMP to check for criminal records, the Canadian Security Intelligence Service to check for terrorist links, and on Customs to determine whether the applicant has had any Customs violations. While the Canadian Security Intelligence Service provides information based on a complete biography of individuals, the RCMP provides only information on whether a person has been charged or convicted of a criminal offence—information that does not identify for Transport Canada whether a person has associations with organized crime or is a refugee claimant. Based on the information it receives, Transport Canada determines whether a security clearance should be issued.

3.141 We reviewed the systems and procedures used by the RCMP and the Canadian Security Intelligence Service for the extent of their screening procedures, timeliness of service, and cost.

3.142 We audited the RCMP's and Customs' active investigation files for five major Canadian international airports (at Halifax, Montréal, Toronto, Calgary, and Vancouver). We also selected a sample of 405 restricted area clearance holders and asked the RCMP to determine whether any of them had significant criminal associations that might warrant a review of their clearance. We thank the RCMP for undertaking this work on our behalf; its knowledge and access to these systems provided for a more efficient examination.

Criminal associations are a significant threat to air transport security

3.143 **Increasing level of criminality.** Transport Canada exercises considerable discretion in the granting of clearances to restricted areas at airports. A criminal record may be the outcome of some offence unlikely to reoccur or to pose a threat to air transport. Individuals with a record of such an offence may be given a security clearance.

3.144 We examined persons holding clearances at five Canadian Airports—Toronto, Montréal, Vancouver, Halifax, and Winnipeg—and found that about 3.5 percent have criminal records. In the general population, 9 percent of Canadians have criminal records. However, based on our analysis about 5.5 percent of clearance holders hired between January 2001 and May 2003 had criminal records. While this is still lower than the Canadian average, the upward trend over the last two years is of concern.

3.145 Transport Canada officials told us that the clearance program focussed on a relatively narrow concept of "unlawful interference with civil aviation," which concentrated on the risks of hijacking and sabotage. This concept has been derived from international conventions. The risks of drug smuggling and other criminal activity were not necessarily regarded as grounds for denial of a clearance.

3.146 **Number of active investigations.** The Canada Customs and Revenue Agency and the RCMP both investigate criminal conspiracies at Canadian airports; generally these involve drug smuggling. We reviewed the investigation files at the five airports we visited. Police and Customs had identified 247 individuals with clearances to restricted areas who were involved in criminal conspiracies, almost all of them in Toronto and Montréal with a few in Vancouver (no such individuals were identified at the airports in Halifax and Calgary). Customs and police officials consider that even a small percentage of clearance holders with criminal intent poses a serious threat. A single criminal may bribe or coerce entire work teams to facilitate smuggling. Those involved rarely know what is being smuggled.

3.147 The RCMP's assessment of clearance holders indicates a greater problem than is indicated in the criminal conspiracy investigation files at airports. At the two airports where police and Customs had no active investigations, clearance holders included individuals who may have significant criminal associations.

3.148 **Extent of criminal association.** Each of the 405 individuals in our sample was assessed for criminal association by the RCMP's Criminal Intelligence Directorate, based on its information in three databases—the Canadian Police Information Centre, the Police Information Retrieval System, and the National Criminal Databank. We asked the RCMP if its intelligence files indicated any associations that might preclude the issuing of a clearance to a restricted area. Such associations would include, for example, membership in a biker gang, a spouse or close relative involved in organized crime, or an address associated with criminal activity. It is important to note that such individuals would not necessarily have a criminal record themselves or be active in organized crime; we also note that none of the 405 clearance holders in our sample had been assessed by Transport Canada for criminal association.

3.149 Based on the results of the RCMP's database search on the 405 persons in our sample (generalized to the total number of people holding clearances to restricted areas at the five airports), we estimate that about 4,500 persons or 5.5 percent have possible criminal associations that warrant further investigation and possibly withdrawal of some security clearances. This represents a serious threat to security at airports.

3.150 In addition to identifying individuals with criminal associations, the RCMP identified 16 businesses operating at airports that were linked to criminal activity such as providing travel arrangements for organized crime, facilitating identity fraud, and selling stolen passes. The firms were associated with biker gangs, organized crime, and drug trafficking. No firms with terrorist associations were discovered. At the two airports where Customs and the RCMP had no active criminal conspiracy investigations, nine companies with criminal links were operating.

3.151 **Recommendation.** Where there is sufficient evidence, the Canada Border Services Agency should support the RCMP in conducting criminal conspiracy investigations at the two airports that had no active cases at the time of our audit.

Canada Border Service Agency's response. CBSA continues to work with our partners to investigate any criminal conspiracy at airports where there is sufficient evidence identified by law enforcement to support such an investigation.

RCMP's response. The RCMP continually assesses the extent of criminal associations and the existence of criminal conspiracies in the course of our business. This is being done at all airports, including the two that did not have current investigations at the time of the audit. Where the RCMP does not have primary jurisdiction of the airport, the assessments are done in conjunction with the police service of primary jurisdiction.

There are no legal barriers to strengthening airport security

3.152 During our audit, various officials told us that there were legal barriers to wider sharing of criminal intelligence information. For example, some mentioned that individuals had a Charter right to freedom of association that precluded denial of a security clearance.

3.153 In our opinion, there are no legal barriers to sharing police data with Transport Canada. However, police and Transport officials may have to assess the trade-off between revealing to an individual that the police have a file on him or her and safeguarding the security of air transportation.

3.154 **Recommendation.** The RCMP and Transport Canada should reconsider the sharing of police intelligence information on criminal associations of applicants for and holders of clearances to restricted areas at airports.

RCMP's response. Agreed. The RCMP is actively consulting with Transport Canada and examining current processes to identify and address gaps or vulnerabilities in the current process of sharing information and intelligence.

Transport Canada's response. Both Transport Canada and the RCMP recognize the importance of sharing police intelligence information on criminal associations of applicants for, and holders of, clearances to restricted areas at airports. Moreover, effective February 16, 2004, the Government of Canada added another layer of security to the nation's aviation system by unveiling a new program to screen non-passengers who are authorized to enter restricted areas at Canada's major airports. Under the program, non-passengers—such as airline personnel, airport employees, refuelers, flight crews, caterers, aircraft groomers, maintenance personnel and ground handlers—are subject to random screening when accessing restricted areas at major airports.

Transport Canada is committed to working with the RCMP and other police forces to help facilitate and improve the sharing of information, while respecting privacy concerns.

3.155 **Recommendation.** Once it has obtained access to complete police information, Transport Canada should begin a comprehensive review of all clearance holders.

Transport Canada's response. Currently, Transport Canada is of the opinion that it is bound by the *Aeronautics Act*, which restricts the scope of the regulations to "preventing unlawful interference with civil aviation" (ss 4.7(2)). The clearance program has focussed on the "unlawful interference with civil aviation" concept (hijacking, sabotage, etc.) derived from international conventions. The risks of drug smuggling and other criminal activity are not necessarily regarded as grounds for denial of a clearance.

The proposed *Public Safety* Act (Bill C-7) would strengthen, clarify, and expand authorities relating to security clearances for transportation workers.

Transport Canada's analysis would suggest that the number of persons with criminal associations who should have their security clearances withdrawn is very small. Should it prove necessary, with the new system that supports the Transportation Security Clearance program, it will be possible for these persons to have their clearances removed in an accelerated manner.

Transport Canada is developing options for implementing a comprehensive review and will also be determining what is needed to achieve it.

Conclusion

3.156 The current management framework of the Public Security and Anti-Terrorism initiative met most of our audit criteria. The vast majority of funds allocated in the 2001 Budget have been channelled to identified priority areas. In addition, the Treasury Board Secretariat is taking care to track spending and is attempting to assess the improvements achieved by the initiative.

3.157 Nevertheless, the management framework failed to ensure improvement in the ability of security information systems to communicate with each other. Consequently, needed improvements have been delayed by several years. Moreover, even as the government was purchasing equipment to digitize the collection of fingerprints and launching programs that would create new demands for fingerprint identification, projects that would have helped it to deal with the increased demand were not included in the initiative.

3.158 We also found deficiencies in the management of intelligence. At the top level, we did not find a strategic framework guiding investment in and development of intelligence information. The government as a whole did not produce adequate lessons-learned assessments of critical incidents such as the September 11 attacks, nor did it develop and follow up on improvement programs. Some agencies have created new co-ordinating mechanisms, but some departments are still not participating in them.

3.159 Watch lists used to screen visa applicants, refugee claimants, and travellers seeking to enter Canada are in disarray. There is no overall quality control of this vital function, which is spread over several departments and agencies. No one monitors delays in entering data or the quality of the information.

3.160 Finally, we found that applicants for clearance to restricted airport areas are not being checked against available intelligence databases. As a result, restricted area clearances are granted to many individuals whose reliability must be questioned. Unless air transportation workers with access to aircraft are reliable, spending for the security of passengers and cargo will be of reduced value.

3.161 Overall, these gaps and deficiencies point to a requirement to strengthen the management framework for security and intelligence. Improvement is especially needed in the management of issues that cross agency boundaries, such as information systems, watch lists, and personnel screening.

About the Audit

Objectives

The objectives of the audit were to

- determine whether the management framework for the Public Security and Anti-Terrorism initiative was adequate to ensure that funding decisions reduced risks to Canadians by the maximum extent possible;
- determine whether intelligence services work efficiently together and provide enforcement personnel with adequate information; and
- determine whether air transportation workers are adequately screened for reliability in a timely manner.

Scope and approach

The scope of the audit included the overall management of the Public Security and Anti-Terrorism initiative, intelligence and information management, and reliability screening for airport restricted area clearances. The audit included all departments and agencies that support the PSAT initiative, but focussed on the Privy Council Office, the Treasury Board Secretariat, Solicitor General Canada, the Canadian Security Intelligence Service, the RCMP, National Defence (including the Communications Security Establishment), the Canada Customs and Revenue Agency, Transport Canada, Citizenship and Immigration Canada, and the Department of Foreign Affairs and International Trade.

We undertook the audit by interviewing headquarters staff of those organizations, reviewing files and records, sampling databases, reviewing audit trails for electronic records, and visiting operational sites such as airports, marine ports, and intelligence offices. We also visited selected officials in the United States and Australia.

Criteria

Our audit was based on the following criteria:

- Funding should be allocated according to an overall intelligence-based threat assessment and a sound appreciation of existing security capabilities.
- Departments'/agencies' progress and performance documents should provide a good basis for co-ordinating and controlling the PSAT initiative.
- Departments should track and report costs related to the PSAT initiative.
- The government should employ appropriate management systems and practices to implement the PSAT initiative in a cost-effective manner.
- Accountability should be defined to resolve disputes in a timely manner, eliminate overlap and duplication, and result in integrated approaches to the production of intelligence.
- Intelligence resources should be allocated consistently and on the basis of a risk assessment.
- Intelligence reports and alerts should reach front-line staff in a timely manner.
- Security and intelligence staff should have systematically assessed the September 11 attacks and other important incidents and improved their capabilities.
- Officials should not unduly withhold information from other agencies when doing so would impair security.
- Transport Canada should be aware of any criminal associations of airport workers granted Restricted Area Access Clearance and other transportation workers granted similar clearances.
- Transport Canada should be able to demonstrate due diligence in its consideration of applicants with incomplete CSIS checks.
- There should be time standards for clearances, established by the needs of the transportation sector.
- CSIS should be resourced to meet response standards.

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Report of the Auditor General of Canada to the House of Commons—March 2004

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2004

Report of the
Auditor General of Canada
to the House of Commons

MARCH

Chapter 4
Canadian Food Inspection Agency—
Regulation of Plants with Novel Traits

Office of the Auditor General of Canada

The March 2004 Report of the Auditor General of Canada comprises seven chapters, a Message from the Auditor General, and Main Points. The main table of contents is found at the end of this publication.

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Ce document est également disponible en français.

© Minister of Public Works and Government Services Canada 2004
Cat. No. FA1-2004/1-4E
ISBN 0-662-36244-6

Chapter

4

Canadian Food Inspection Agency

Regulation of Plants with Novel Traits

All of the audit work in this chapter was conducted in accordance with the standards for assurance engagements set by the Canadian Institute of Chartered Accountants. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.

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Canadian Food Inspection Agency
Regulation of Plants with Novel Traits

Main Points

4.1 The Canadian Food Inspection Agency regulates the environmental release of plants developed through biotechnology, which are included in a broad category called plants with novel traits. Our audit identified weaknesses in the Agency's practices related to the management of risks associated with the environmental release of these plants. Our findings raise concerns that the Agency may not be regulating the unconfined release of these plants in a consistent manner.

4.2 Our audit focussed on the processes that the Canadian Food Inspection Agency had in place to ensure that it was meeting its responsibilities with respect to the regulation of plants with novel traits. As such, our audit procedures were not designed to determine whether undeclared and undetected plants with novel traits were entering Canada, whether any unauthorized ornamental plants with novel traits were present in Canada, or whether the Agency had approved any plants with novel traits that should not have been. No information came to our attention that any of these situations had occurred.

4.3 Our findings provide an early warning signal that some important aspects of the Agency's regulatory processes for plants with novel traits need strengthening. Given that the next generation of plants with novel traits could pose new and more complex environmental risks, it is important that the Agency act on our recommendations if it is to be prepared to meet these future challenges.

4.4 We found that there is a risk that undeclared and undetected plants with novel traits could be imported into Canada, and may therefore escape Canada's regulatory system. There is also a risk that unapproved ornamental plants with novel traits could be present in Canada.

4.5 The Agency has required insect resistance management as a condition whenever it authorizes insect-resistant plants with novel traits. However, the Agency's audits of conditions for unconfined release of insect-resistant corn have not yet enabled it to fully verify compliance with the conditions imposed.

4.6 To maintain quality and consistency in the delivery of the regulatory program for plants with novel traits, we would expect the Agency to have documented and implemented a quality management system to guide its evaluations. To support its decisions regarding unconfined release, we found deficiencies in standard operating procedures, a lack of complete documentation in the files, and incomplete definition of data quality standards to guide the evaluations. For example we found that the Agency did not have complete documentary evidence and, therefore, was not transparent about how it was evaluating the long-term effects on the environment before authorizing unconfined release of plants with novel traits.

Background and other observations

4.7 The Government of Canada has identified biotechnology as a key industry for economic growth and international competitiveness. Consequently it has invested heavily in research, promotion, economic development, and the regulation of biotechnology.

4.8 Three federal organizations currently share responsibility for regulating products developed through biotechnology for their potential effects on health and the environment. This audit focussed on the Agency's regulatory activities to manage the environmental risks of plants with novel traits, a broad category that includes plants developed through biotechnology. The Agency states that Canada is the only country to use this regulatory approach.

4.9 Having and implementing a strong regulatory framework is essential if Canada is to capitalize on the potential benefits of plants with novel traits while appropriately managing the potential risks. Approval of a plant with a novel trait that harms the environment or human health could undermine public confidence in the regulatory system.

The Agency has responded. The Agency agrees with our recommendations. Plans and actions it has underway are indicated in the responses in the chapter.

Introduction

4.10 The Government of Canada has identified biotechnology as a key industry for economic growth and international competitiveness. Consequently it has invested heavily in research, promotion, economic development, and the regulation of biotechnology (Exhibit 4.1 provides some recent examples). Biotechnology has been broadly defined as the use of biological processes, especially genetic manipulation, for industrial and other purposes. It can refer to traditional as well as modern processes. Most often, the term biotechnology is used interchangeably with modern biotechnology. In this chapter we use biotechnology to mean modern biotechnology (for more details see Biotechnology on page 8).

Federal role in biotechnology

4.11 The federal government fulfils many roles related to biotechnology, including

- regulating products,
- conducting in-house government research and supporting private sector research,
- promoting the economic development of the industry, and
- providing information to the public.

Exhibit 4.1 Examples of federal investment in biotechnology

Organization or program	Amount
Technology Partnerships Canada A technology investment fund in Industry Canada that supports research, development, and innovation through repayable contributions	Technology Partnerships Canada has approved provision of $263 million in repayable contributions to biotechnology projects since its launch in 1996
Expenditures on biotechnology research and development (in-house and external)	Ongoing For example: $492 million for 2001–02
Genome Canada Involved in developing and implementing a national strategy to help develop the biotechnology industry	$375 million to date
Canadian Biotechnology Strategy	$28.56 million from 2002–03 to 2004–05
Funding to strengthen the federal regulatory system for biotechnology	$90 million between 2000–01 and 2002–03 $34.6 million per year starting in 2003–04

Note: Figures not audited by the Office of the Auditor General

Source: Government of Canada publications

4.12 **Research and development.** Several federal organizations are involved in research, or the development of biotechnology. Examples include Agriculture and Agri-Food Canada, Industry Canada, the National Research Council, and Natural Resources Canada.

4.13 **Regulating products.** Three federal organizations currently share responsibility for regulating products developed through biotechnology: Health Canada, the Canadian Food Inspection Agency, and Environment Canada. These organizations evaluate the potential effects on health and the environment of products developed through biotechnology. They are also involved in research activities to support their regulatory roles. Fisheries and Oceans is developing regulations under the *Fisheries Act* to regulate aquatic organisms with novel traits, including fish developed through biotechnology.

4.14 **Regulating food.** Federal responsibility for regulating food, including food developed through biotechnology, is shared by Health Canada and the Canadian Food Inspection Agency (the Agency). Health Canada is responsible for establishing standards and policies governing the safety and the nutritional quality of food and developing labelling policies related to health and nutrition. The Agency is responsible for policy development for non-health and safety-related labelling (misrepresentation and fraud), and enforcement of this policy, including inspection. It also enforces Health Canada's health and safety-related food labelling policies. In addition, Health Canada is responsible for regulating pest control products and the human safety of drugs, medical devices, and cosmetics developed through biotechnology. The Agency is responsible for regulating plants, animal feeds, fertilizers, and veterinary biologics (for example, vaccines for animals) developed through biotechnology.

4.15 **Regulating products not regulated under other acts.** Products developed through biotechnology not regulated under other acts are regulated by Environment Canada under the *Canadian Environmental Protection Act, 1999*. The assessment responsibility is shared: Environment Canada evaluates the effects on the environment, and Health Canada evaluates the effects on human health.

4.16 **National Biotechnology Strategy.** In 1983 the government developed the first National Biotechnology Strategy, which focussed on research and development, the availability of skilled workers, communication and collaboration between researchers, and creating a favourable climate for private sector investment.

4.17 In 1993, the government outlined its principles for regulating biotechnology:

- maintaining Canada's high standards for protecting the health of Canadians and the environment;
- using existing laws and regulatory departments to avoid duplication;
- developing clear guidelines that are in harmony with national priorities and international standards for evaluating biotechnology products;

- providing a sound, scientific knowledge base on which to assess risk and evaluate products;
- ensuring that the development and enforcement of Canadian biotechnology regulations are open and include consultation; and
- contributing to the prosperity and well-being of Canadians by fostering a favourable climate for investment, development, innovation, and the adoption of sustainable Canadian biotechnology products and processes.

4.18 **Canadian Biotechnology Strategy.** In 1998 the National Biotechnology Strategy was updated as the Canadian Biotechnology Strategy. The current approach to biotechnology builds on the earlier strategy, which had been more narrowly focussed on the economic aspects of biotechnology. The Canadian Biotechnology Strategy was designed to specifically address the regulatory and ethical dimensions of biotechnology. The vision of the new strategy is:

> to enhance the quality of life of Canadians in terms of health, safety, the environment, and social and economic development by positioning Canada as a responsible world leader in biotechnology.

The Canadian Food Inspection Agency regulates plants with novel traits

4.19 The Canadian Food Inspection Agency regulates the environmental release of plants developed through biotechnology, which are included in a broad category called plants with novel traits (PNTs).

Plants with novel traits—"A plant variety possessing a characteristic that is intentionally selected or created through a specific genetic change and is either not previously associated with a distinct and stable population of the plant species in Canada or expressed outside the normal range of a similar existing characteristic in the plant species."—Canadian Food Inspection Agency

4.20 The Agency, through the Plant Biosafety Office, regulates all plants with novel traits primarily under the Seeds Regulations Part V. PNTs could be agricultural, horticultural, or ornamental plants; or forest trees. The Agency also regulates imported PNTs under the *Plant Protection Act*; its purpose is to control pests to plants. Under this Act, the Agency grants permits for importing PNTs.

4.21 The 1993 Federal Regulatory Framework for Biotechnology established that it is the final plant product that determines the potential risk to the environment, not whether the plant was developed through traditional or more modern processes. Therefore, plants with novel traits are regulated in the same way, no matter how they were developed. The Agency states that Canada is the only country to use this regulatory approach. Other countries regulate new plants based on the process used to create them.

Did you know?

Plants with novel traits have been regulated in Canada since 1988.

A Statistics Canada report *VISTA on the Agri-Food Industry and the Farm Community, December 2002* shows that almost a third of the corn and soybeans grown in both Ontario and Quebec in 2002 were varieties with novel traits.

The Canola Council of Canada estimates that in 2001 approximately 80 percent of the canola acreage harvested in Canada was from plants with novel traits.

(Figures not audited by the Office of the Auditor General.)

4.22 PNTs cannot be legally released into the environment in Canada unless authorized by the Agency. Proponents (that is, companies or individuals) apply to the Agency for authorization for either confined or unconfined release into the environment. Authorization for confined release allows proponents to conduct field-research on PNTs under controlled conditions. Authorization for unconfined release is one of the regulatory approvals needed before plants with novel traits can be sold for widespread planting in Canada.

Toxic—According to the Seeds Regulations Part V, a PNT "is toxic if it is entering or may enter the environment in a quantity or concentration, or under conditions that (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity; (b) constitute or may constitute a danger to the environment on which life depends; or (c) constitute or may constitute a danger in Canada to human life or health."

Did you know?

According to the Canadian Food Inspection Agency's Plant Biosafety Office, it or its predecessor in Agriculture and Agri-Food Canada:

- authorized 5,862 confined field trials of plants with novel traits for research purposes (includes only trials that took place) from 1988 to 2003
- issued 41 letters authorizing the unconfined release of plants with novel traits under the Seeds Regulations Part V from 1995 to 2003
- percentage of the unconfined releases that were for plants with novel traits produced through recombinant DNA biotechnology: **about 85 percent**
- percentage of the total number of unconfined releases that were for plants with novel traits tolerant to herbicides or resistant to insect pests: **about 85 percent**

4.23 The Seeds Regulations Part V require the Agency to evaluate the risks to the environment before approving PNTs for either confined or unconfined release. This includes the requirement to assess whether PNTs are toxic. The Agency bases its evaluations primarily on data submitted by proponents, the Agency's information on the unchanged plant species, scientific information in the public domain, research contracted by the Agency, and where necessary, consultations with external experts. The Agency's Regulatory Directives outline the evaluation criteria and the information required from proponents to support their PNT applications.

4.24 Exhibit 4.2 lists the environmental safety assessment criteria used by the Agency prior to authorizing the release of PNTs. It also explains some of the potential effects of PNTs on the environment. The Agency expects to soon receive applications for new PNTs that will likely have different risks, and therefore may pose new regulatory challenges.

4.25 The Agency has the authority to place conditions to manage the risks to the environment when it approves the environmental release of PNTs. Conditions for confined release include restricting the size and number of the field trials, using measures to prevent the spread of pollen and seeds, requiring proponents to monitor the trial sites, and restricting how the land may be used afterwards. Agency inspectors visit the trial sites to verify whether proponents are complying with the conditions. The Agency has also placed conditions on certain authorizations of PNTs for unconfined release, and has in some cases monitored compliance with these conditions.

4.26 Having and implementing a strong regulatory framework is essential if Canada is to capitalize on the potential benefits of plants with novel traits while appropriately managing the potential risks. Approval of a plant with a novel trait that harms the environment or human health could undermine public confidence in the regulatory system.

Focus of the audit

4.27 We focussed our first major audit of biotechnology on the federal government's regulatory activities to manage the environmental risks of plants with novel traits, a broad category that includes plants developed through biotechnology. The Canadian Food Inspection Agency has assessed many of the products currently on the market that required environmental assessments. Therefore our Office decided to audit the regulatory activities of the Agency's Plant Biosafety Office. It, or its predecessor in Agriculture and Agri-Food Canada, has been regulating the environmental release of plants with novel traits since 1988. Further details about our scope and approach can be found in **About the Audit** at the end of this chapter.

Exhibit 4.2 How the Agency assesses the environmental safety of plants with novel traits

Environmental safety assessment criteria	Reasons for criteria
"potential of the PNT to become a weed of agriculture or be invasive of natural habitats"	Weeds are usually defined as plants growing where they are not wanted. Weediness may be increased by changing the "fitness" characteristics of a plant. These characteristics could help the plant outcompete other plants. Some examples include • the ability of the plant to resist diseases or pests, • the ability of the plant to resist cold or survive the winter, and • the amount of seed a plant produces, or its ability to produce seed earlier than other plants.
"potential for gene-flow to wild relatives whose hybrid offspring may become more weedy or more invasive"	Plants spread their genes by pollen and seed dispersal. The extent of gene flow depends on the plant's biology, whether there are related plants growing in Canada, and the way the plant is managed when cultivated as a crop.
"potential for the PNT to become a plant pest"	Plants can act as hosts for diseases that can spread to other plants. For example, could genetic recombination in a novel virus-tolerant plant result in a plant virus with an enhanced ability to infect plants?
"potential impact of the PNT or its gene products on non-target species, including humans"	Plants that are grown in the environment will come into contact with a wide range of organisms, from soil microbes to humans. PNTs could have unintended, negative effects on some organisms.
"potential impact on biodiversity"	Biodiversity can be defined as the number and variety of organisms (species) within a geographic region. Organisms are linked in an ecosystem in complex ways, for example, through food chains. Therefore, changes in biodiversity could affect many other organisms.

Source: Canadian Food Inspection Agency

Biotechnology

What is it?

Biotechnology has been broadly defined as the use of biological processes, especially genetic manipulation, for industrial and other purposes. Biotechnology can refer to traditional as well as modern processes. However, the term modern biotechnology is often used to denote one category of biotechnology called recombinant DNA technology. This technology enables scientists to directly transfer specific genetic traits from one organism to another, including between species that would not naturally interbreed. Most often, the term biotechnology is used interchangeably with modern biotechnology. In this chapter we use the term biotechnology to mean this category of modern biotechnology.

Did you know?

People use many different terms to refer to plants, foods, or other products that have been developed through modern biotechnology:

- genetically modified (GM)
- GM plants, GM foods, or genetically modified organisms (GMOs)
- genetically engineered (GE)
- recombinant DNA (rDNA)
- transgenic

Why should Canadians care?

People hold differing opinions about biotechnology. In preparing for this audit, we found that some stakeholders were more interested in the potential benefits, and some were more concerned about the potential risks.

Overall the Canadian biotechnology sector is growing rapidly. Statistics Canada's *Biotechnology Use and Development Survey—2001* shows that between 1997 and 2001

- the number of "innovative biotechnology firms" increased from 282 to 375, and
- the number of "biotechnology products and processes" on the market from these firms increased from 1,752 to 9,661.

However, this survey notes that the agriculture biotechnology sector declined from 90 firms in 1999 to 65 in 2001. It attributes this decline to several factors: consolidation of firms, firms shifting from the agriculture sector to the food processing sector, and, to a lesser degree, fewer firms because some ceased operations.

The same survey indicates the contribution of innovative biotechnology firms to the economy in 2001

- 49 percent of the sector's 11,897 people employed in biotechnology-related positions were in highly skilled jobs in the scientific research/direction, and technician categories; and
- the agriculture biotechnology sector had 3,498 products and processes in the research and development phase, compared to 2,017 human health products and processes in the same phase.

Benefits. The federal government's *1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process* notes that biotechnology has the potential to generate important new economic, environmental, and health benefits. Such potential benefits could include

- new products to remedy environmental contamination,
- more effective treatments for life-threatening diseases,
- improved crop yields,
- improved food quality, and
- increased use of agricultural practices that are more environmentally friendly.

The Strategy also notes that some of these benefits have already been realized. In addition, biotechnology is expected to play a key role in ensuring that Canada's agri-food sector remains competitive internationally.

Risks. However, concerns have been expressed about the potential social, ethical, and economic risks of biotechnology. For example, there is a risk that agricultural products developed through biotechnology that have been approved in Canada will not be approved in other countries. Therefore Canada may need to be able to segregate biotechnology from non-biotechnology crop products to protect its export markets. Another potential economic risk is the presence of pollen or seeds from biotechnology-derived crops in organic or non-biotechnology crops.

There are also concerns about the potential impacts on the environment, and the potential health effects of products developed through biotechnology. Furthermore, plants may be modified to produce medical products, for example, drugs and vaccines, or industrial products such as biodegradable plastics and lubricant oils. These plants could pose different environmental or health risks.

Observations and Recommendations

4.28 A regulatory system must capture all products that are required to be submitted for approval. The Canadian Food Inspection Agency regulates both imported and domestically produced plants with novel traits (PNTs) that are released into the environment. We therefore examined the Agency's procedures relating to imported PNTs. Since the regulations apply to all plant species, we also examined the Agency's oversight of ornamental plants with novel traits.

4.29 The Agency's evaluation process should adhere to key principles for maintaining quality and consistency. We examined whether quality management principles are built into the overall evaluation process for unconfined release, including how the Agency protects the confidential business information submitted by proponents. We also examined the Agency's documentary evidence for the aspects of its evaluations related to the long-term environmental effects of PNTs.

4.30 The Agency may impose conditions on proponents to manage the environmental risks, and should know whether these conditions are being complied with. Thus we examined the Agency's approach for monitoring compliance with conditions after PNTs are authorized for unconfined release. Finally, we assessed the clarity of the regulatory framework.

Imports and ornamentals

Risk that some imported plants with novel traits may be escaping regulation

4.31 Under the *Plant Protection Act* and its Regulations, the Canadian Food Inspection Agency requires importers to obtain a permit before importing plants with novel traits (PNTs) into Canada. The Seeds Regulations Part V apply to all PNTs that are imported and released into the environment. The Agency's Plant Biosafety Office and its predecessor have overseen the import of PNTs since 1988.

4.32 The Agency uses the permit process to identify whether legally imported plants are PNTs and hence subject to the Seeds Regulations Part V. The Agency said that it obtains information on unapproved PNTs that could be imported into Canada, from regulatory authorities in other countries, industry intelligence, and international organizations.

4.33 We expected that the Agency's activities and decisions would support the achievement of the environmental safety objectives and goals of the regulatory program for PNTs. We therefore examined whether the Agency's approach to regulating imports enables it to effectively identify whether imported plants are PNTs.

4.34 At the time of our audit, we found that, instead of using the term "plant with a novel trait," the import permit application form asked importers to declare whether the plant is a "product of biotechnology." When the information provided indicates that the plant could be a PNT, Agency officials send the applications to the Plant Biosafety Office for review. The Agency told us that it relies on the import permit system to correctly identify

Did you know?

According to the Canadian Food Inspection Agency:

- the number of new plant import permits that the Agency issues each year: **about 6,000**
- in 2002–03, the value of plants and plant products imported into Canada: **about $10 billion**

whether an imported plant is a PNT. Thus, in our opinion, importers' awareness of their legal responsibilities, and the questions asked on the import permit application form, including the guide attached to it, are critical to helping importers accurately complete the form.

4.35 We found that neither the import permit application form nor the attached one-page guide defined "product of biotechnology." The Agency has 95 active policy directives on imports on its Web site. While one of the policy directives provided further information on importing PNTs and defined what a plant with a novel trait is, neither the form nor the attached guide referred importers to this directive. In our opinion, the importance of the requirements regarding PNT imports warrants making the requirements more accessible to importers, for example, by referring to the directive either on the application form or in the attached guide.

Testing for plants with novel traits is difficult

The Agency acknowledged that it is difficult to determine whether imported plants are plants with novel traits (PNTs). This is because there is no practical or cost-effective method to test for them. In general, PNTs are not visibly different from their non-PNT counterparts. While scientific methods to detect some PNTs are available, these methods are unique for each product of biotechnology, because the methods detect only specific genes, proteins, or traits. Testing would require knowledge of all the novel genes, proteins, or traits of all species of all the plants and plant products being imported into Canada.

4.36 Agency officials acknowledged that one could interpret "product of biotechnology" as being narrower in scope than the definition of a plant with a novel trait in the Seeds Regulations Part V. However, a recently added explanation to the application form did not sufficiently clarify that importers must declare whether the plants were PNTs. Moreover, this addition was inconsistent with the definition of biotechnology in the policy directive on PNT imports.

4.37 If importers declared the plants to be products of biotechnology, they were asked to provide detailed technical information on the novel traits. If importers did not declare the plants to be products of biotechnology, or did not provide details in the supporting information that suggested the product could be a PNT, the Agency told us that it had no basis to investigate further. The exception would be where other sources of information suggest that further investigation is warranted. In our opinion, the information that the Agency obtains from others is only helpful if the information provided by importers indicates that the plants could be unapproved PNTs. Nevertheless, the Agency provided several examples where it had detected and taken action to remove illegally imported products of biotechnology.

4.38 Regulating PNT imports is challenging. This is due to Canada's unique approach based on plants with novel traits, the volume of imports of plants and plant products entering the country, and the fact that importers include medium to large companies, small businesses, individuals, and the public sector. We are concerned that there is a risk that undeclared and undetected PNTs could be imported into Canada and may therefore escape Canada's regulatory system. While no information came to our attention that undeclared and undetected PNTs are entering the country, the Agency concedes that, although unlikely, this is possible.

4.39 **Recommendation.** The Canadian Food Inspection Agency should improve its communications to importers to better enable them to indicate whether the plants they are importing are plants with novel traits.

Agency's response. The Agency agrees to continue to enhance communication with importers. While no information has been presented that undeclared and undetected PNTs are entering the country, importer awareness continues to be a key component of the Agency's compliance strategy. As such, several communication channels are already available for importers including, for example, the Agency's Web site, the import permit office, and the publication of Regulatory Directives. The Agency will continue to assess what additional information may help importers in better understanding their responsibility.

Risks posed by ornamental plants with novel traits need to be more formally assessed

4.40 According to the Agency, the Seeds Regulations Part V apply to the environmental release of all plant species with novel traits, including ornamental plants with novel traits. The Canadian ornamental industry includes producers (including breeders), retailers, and importers of: nursery bedding plants, ornamental shrubs and trees, potted plants, cut flowers, and seeds.

4.41 We expected that the Agency's activities and decisions on ornamental plants would support the achievement of the environmental safety objectives and goals of the regulatory program for plants with novel traits (PNTs). We therefore examined how the Agency regulates both imported and domestically grown ornamental PNTs.

4.42 To prevent unauthorized release of PNTs in Canada, the Agency told us that it relies on the proponents' obligation to understand and voluntarily abide by the regulatory requirements for PNTs. It also relies on complaints from members of the industry who expect a level regulatory playing field. In our opinion, this approach is only effective if members of the industry are fully aware of the regulatory requirements.

4.43 However, the minutes from one of the Agency's consultations in May 2002, noted that the domestic "ornamental horticultural industry lacks awareness of the [PNT] regulations." The Agency also stated in a funding request for 2003–04, that the ornamental industry has been "undertaking plant breeding for a long time without such [PNT] regulation and are generally not aware of the regulatory implications of novel traits in their products." The Agency has made some effort to inform industry representatives of the Canadian ornamental sector about the regulation of PNTs. While these efforts were worthwhile, we are concerned whether the actions the Agency has taken to date are sufficient to adequately address the issues. We are therefore also concerned that domestic producers of ornamental PNTs, who are unaware of the Seeds Regulations Part V, may not submit applications for confined or unconfined release. As previously discussed, there is also a risk that importers may not always declare whether ornamental plants are PNTs in their applications for import permits.

4.44 The Agency told us that it has never received an application for either confined or unconfined release of an ornamental PNT; nor has it received any complaints about the unauthorized release of ornamental PNTs. While no information came to our attention that unauthorized ornamental PNTs are present in Canada, other countries have approved them, and research is underway in Canadian laboratories to produce some. We note that a large number of species have been bred to produce an enormous variety of ornamentals. In our opinion, this, along with the indications that the domestic ornamental industry lacks awareness of the regulatory program for PNTs, suggest that there is a risk that unapproved ornamental PNTs could be present in Canada. We therefore expected the Agency to be able to demonstrate that it has assessed the potential risks that different kinds of ornamental PNTs could pose to the environment.

4.45 While we found that the Agency expects the environmental release of some ornamental PNTs to have different impacts than agricultural crops, it has not yet identified the environmental risks that ornamental PNTs could pose. The Agency says this is because it has not yet received an application for an ornamental PNT. However, in our view, more formally and systematically identifying the ornamental species that pose the highest risks to the environment would provide a basis to focus the Agency's regulation of imported ornamental PNTs and its efforts to educate the industry. The Agency has made an effort to be more proactive regarding the regulation of ornamental PNTs, because it requested funds from the Canadian Biotechnology Strategy for 2003–04 to consult with the ornamental industry on the environmental safety issues related to ornamental PNTs. However, the project was not funded.

4.46 **Recommendation.** The Canadian Food Inspection Agency should more formally and more systematically identify the environmental safety issues related to the environmental release of ornamental plants with novel traits.

Agency's response. The Agency concurs that a more formal and systematic approach could be used to determine the extent to which breeders are actually producing ornamental plants with novel traits. The Agency currently adopts a case-by-case approach to the environmental safety analysis of PNTs, which is universally accepted by regulatory agencies throughout the world. Nevertheless, the Agency will continue to formalize its evaluation processes.

4.47 **Recommendation.** Based on the environmental safety issues, the Canadian Food Inspection Agency should develop appropriate approaches for its assessment and regulation of environmental release of ornamental plant species with novel traits.

Agency's response. The Agency agrees that, based on a formal and systematic assessment of the ornamental plant industry, it will determine whether new regulatory approaches are required. As acknowledged in this report, there is currently no evidence that unauthorized ornamental PNTs are present within Canada. The Agency remains committed to working diligently to implement additional measures where warranted.

4.48 **Recommendation.** The Canadian Food Inspection Agency should enhance its efforts to educate the Canadian ornamental industry of its responsibilities under the Seeds Regulations Part V.

Agency's response. The Agency agrees with the recommendation and will continue to provide information to the ornamental industry. To date, there have been considerable efforts in working with ornamental industry associations. The Agency will also endeavor to undertake initiatives that will reach the growers of ornamental plants.

Procedures to evaluate environmental release

4.49 We would expect the Canadian Food Inspection Agency to have documented and implemented a system to maintain the quality and consistency of its evaluations of plants with novel traits (PNTs). The system should incorporate consolidated, complete, and current standard operating procedures, including standards for data quality. Furthermore, activities and decisions of the Agency's program to regulate plants with novel traits should be clearly documented throughout the process. The files should also include evidence of appropriate management challenge, review, and approval.

4.50 Clear and complete documentation of the Agency's analyses and conclusions is important in our opinion because

- the evaluations for unconfined release often represent months of complex scientific effort that require significant use of professional judgement,
- the decisions of the Agency could become the subject of litigation and the Agency may be required to be able to demonstrate to the courts that it had exercised appropriate diligence in carrying out its mandate for regulating PNTs, and
- the efficient analysis of any new information provided after authorization of unconfined release may be dependent on sound documentation of the original evaluation.

4.51 We therefore examined the Agency's procedures for evaluating environmental effects prior to approving confined and unconfined release. We also examined the files for all 19 PNT applications for unconfined release, submitted to, and evaluated by the Agency since its formation in 1997. In addition, we examined 10 of the 43 application files for confined release that the Agency received in 2002. We looked for clear evidence that the Agency has implemented a system to maintain the quality and consistency of its evaluations of PNTs.

Significant improvements needed in controls over evaluation procedures for unconfined release

4.52 We found that the Agency has standard operating procedures for evaluating applications for confined release that are relatively complete and documented. However, at the time of our audit, the Agency did not have complete, up-to-date, standard operating procedures to guide its evaluations of applications for unconfined release.

4.53 We did not assess the quality of the scientific data submitted by proponents or the scientific rigour of the Agency's evaluations for unconfined release. However we did assess the quality of the documentation in the internal files and electronic database for the Agency's analyses and decisions.

We found that the documentation in the files generally comprised correspondence, data supplied by the proponents, and "deficiency letters" sent to proponents by the Agency requesting additional data. The files also showed that the Agency had, on occasion, consulted with external scientists about specific aspects of the evaluations of plants with novel traits (PNTs).

4.54 We also found that the Agency's public-decision documents provided some summary information about its evaluations and conclusions regarding unconfined release. However, the Agency's internal files did not provide a comprehensive record of the analyses that supported the summary information or the conclusions in the public-decision documents. Furthermore, in many cases, the files for the evaluations of unconfined release lacked key documents and were poorly organized. In our opinion, this would make it difficult to conduct a detailed review of the steps and rationales leading to the Agency's decisions. An example of the Agency's lack of documentary evidence is further discussed in the next section. In contrast, the Agency's files for confined release were relatively complete and well-organized.

4.55 The Agency requires that data submitted by proponents to support their applications for unconfined release "be produced using statistically valid experimental designs and protocols (that are equivalent to the standards required for inclusion in peer-reviewed research publications)." However, we noted that standards in published journals may vary. A document called the Reviewers' Checklists outlines quality standards for the evaluation of certain analytical techniques used by proponents. While the Agency states that the document was developed to be used by reviewers in the assessment process, we found only one direct reference to it in the Agency's internal files.

4.56 We also found that, other than the Reviewers' Checklists, the Agency has not clearly defined what it means by data "equivalent to the standards required for inclusion in peer-reviewed research publications." Nonetheless, we found that the Agency routinely issues deficiency letters when it considers data submitted by proponents to be incomplete. These letters require proponents to submit additional or modified data, and some of these letters request information outlined in the Reviewers' Checklists.

4.57 Together, the above practices indicate that the Agency employs some standards for data quality in its evaluations of PNTs. However, we found little direct evidence that the standards in the Reviewers' Checklists had been consistently applied. Further, in our opinion, the Agency needs quality standards for the types of data not included in the Reviewers' Checklists, to provide a basis for ensuring consistency in its evaluations.

4.58 The Agency claimed that in addition to the Reviewers' Checklists, it maintains consistency in the quality of its reviews through the scientific expertise of its evaluators, staff training, and intra- and inter-departmental meetings to discuss data quality and to challenge reviewers' conclusions. The Agency was able to show us that it collaborates with other federal organizations and with other divisions within the Agency on certain aspects of the PNT evaluations and decisions. However, in our review of the

Agency's files, we found no formal records of meetings within the Plant Biosafety Office to discuss the quality of the environmental safety data or to challenge the overall conclusions for unconfined release. While a director signs the final letter to proponents that authorizes the unconfined release of a PNT, we found little other documentary evidence of systematic ongoing management review and challenge of evaluators' analyses and decisions.

4.59 The Agency told us that it takes about one year to train evaluators, during which time it says they are paired with a more experienced staff member. However, a review of statistics since the Agency was created in 1997 indicates that Plant Biosafety Office evaluators leave after working there for an average of 24 months. Thus, given the high rate of turnover, detailed documentation of the results and supervisory review of the evaluations are important.

4.60 In conclusion, for unconfined release, we found deficiencies in standard operating procedures, a lack of complete documentation in the files, and incomplete definition of data quality standards to guide evaluations. Consequently, in our opinion the Agency cannot demonstrate through its internal documentary evidence that it is consistently applying quality management procedures in its evaluations of applications for the unconfined release of PNTs. Furthermore, improvements in quality management will become even more important in the future because the Agency expects applications for PNTs to increase in complexity.

4.61 **Recommendation.** The Canadian Food Inspection Agency should develop, approve, and implement written procedures to guide the evaluation, approval, and documentation of applications for unconfined release of plants with novel traits. The procedures should include some provision for formal, systematic, and documented reviews prior to making final decisions.

Agency's response. The Agency concurs with this recommendation. As noted in the report, the Agency currently has standard operating procedures for confined research field trials. In addition, it has already taken actions to fully document its standard operating procedures for unconfined environmental release assessment. In this regard, the procedures also contain provisions for the documentation of reviews prior to final decisions, while still allowing the assessment of products on a case-by-case basis. This approach continues to enable the Agency to collect the necessary information to address risks that could vary depending on the product being assessed.

Lack of documentation on how long-term environmental effects are evaluated before unconfined release is approved

4.62 The Seeds Regulations Part V require the Canadian Food Inspection Agency to evaluate whether plants with novel traits (PNTs) "have or may have an immediate or long-term harmful effect on the environment or its biological diversity" before authorizing confined or unconfined release. We focussed our examination on the Agency's documentation supporting how it evaluates long-term environmental effects. Our results provide additional evidence of the findings discussed in the previous section.

4.63 We found that the Agency has not formally interpreted the phrase "long-term" from the Seeds Regulations Part V. The Agency states that this is because the duration of environmental effects could vary depending on the species, novel trait, and end use of the PNT. Further, the Agency argues that the evaluation of long-term environmental effects is implicit in each of the five assessment criteria that the Agency uses to structure its evaluations of environmental safety.

4.64 The Agency also states that it takes a case-by-case approach in its evaluation of each individual application. To do this, the Agency told us that it extrapolates the potential long-term environmental effects based on

- data submitted by proponents from laboratory studies and confined research field studies conducted for a number of years in various geographic locations,
- the Agency's biology documents that describe the unchanged parent crop and the Agency's knowledge of the novel trait, and
- information published in scientific journals, as well as a number of scientific reports that the Agency has recently commissioned on the environmental effects of PNTs.

4.65 Therefore, based on the considerations cited above, we expected to find specific evidence in its internal files of the Agency's extrapolations with respect to long-term effects, including its analyses and conclusions. However, its internal files and electronic database for unconfined release applications did not contain a complete record of how it reached conclusions about long-term environmental effects. For example, while the Agency's database includes fields for summarizing the type and duration of effects, these fields were not completely filled out in 8 of the 19 database records that we examined. For another six applications, very little or no scientific data or rationale was provided. The remaining five applications were withdrawn.

4.66 An additional safety measure is the mandatory requirement of the Seeds Regulations Part V for proponents to report unexpected effects after a PNT is authorized for unconfined release. We found that "new information" had been provided three times, and in each case, the new information was about the genetics of the PNT rather than any direct environmental effects. The Agency told us that in each case, the new information did not change the Agency's original conclusions about the environmental safety of the PNTs. However, the Agency is still required under the Seeds Regulations Part V to assess whether PNTs have or may have long-term harmful effects on the environment before approving unconfined environmental release.

4.67 In conclusion, from our review of the documentary evidence in the files for unconfined release, it was not transparent how the Agency evaluates the long-term environmental effects before authorizing unconfined release as legally required.

4.68 **Recommendation.** The Canadian Food Inspection Agency should define more explicitly how its evaluation process considers the long-term effects on the environment.

Agency's response. The evaluation of long-term effects has always been a key component in the assessment and approval of PNTs. Nevertheless, the Agency agrees that better communication is needed to more explicitly define how long-term environmental effects of plants with novel traits are assessed prior to approval. The Agency will also provide more information on the measures it has in place to monitor, following the approval, the unintended long-term impacts of plants with novel traits.

4.69 **Recommendation.** The Canadian Food Inspection Agency should also ensure that it has documentary evidence in its files showing how it is evaluating the environmental effects of plants with novel traits, including the long-term effects.

Agency's response. The Agency agrees with the recommendation and will continue to enhance its procedures. The Agency has already made significant progress in updating its documentation to reflect the recent changes to the Regulatory Directives. The procedures also clarify how the documentary evidence in support of the assessments should be organized.

Post-authorization monitoring

4.70 When it authorizes unconfined release of plants with novel traits (PNTs), the Canadian Food Inspection Agency may impose conditions on proponents to manage the environmental risks. The Agency says that proponents in turn may impose related conditions in their agreements with those who grow the PNTs, that is, the growers. We expected that the Agency's post-authorization activities and decisions would support the achievement of the environmental safety objectives and goals of its regulatory program for PNTs. In our opinion, if the Agency is imposing conditions it should know whether proponents and growers are complying.

4.71 Therefore we examined whether the Agency had an approach that enables it to verify compliance with conditions for unconfined release. Effective monitoring after authorization could become even more important if the Agency imposes conditions when it approves the next generation of plants with novel traits.

More assurance of grower compliance with insect resistance conditions for corn needed

4.72 Since 1995, the Agency's Plant Biosafety Office and its predecessor in Agriculture and Agri-Food Canada, have issued 14 authorizations to 7 companies for the unconfined release of insect-resistant plants with novel traits (PNTs). These plants contain proteins, referred to as "Bt" that are known to be toxic to certain types of insects, and which act as insecticides. The Agency says that insect resistance to these toxins could develop over time. Consequently, the benefits of the toxin could be lost, both when used in insect-resistant crops and when applied as a pesticide spray.

4.73 In an attempt to reduce or delay the development of resistance, the Agency has required insect resistance management as a condition of its authorizations of insect-resistant PNTs. Both proponents and growers play a role in preventing the development of insect resistance. This is because insect resistance management includes educating seed companies and growers about preventing the development of insect resistance, monitoring for the development of resistance, having procedures to respond to development of unexpected insect resistance, and using specific farming practices. However, in the event of non-compliance with the conditions, the Agency is only able to take action against proponents because it has no legal authority to enforce compliance by growers.

4.74 In examining the Agency's monitoring of compliance with the conditions to prevent the development of insect resistance, we reviewed the Agency's reports on

- two audits of conditions for unconfined release conducted in 2000, one for PNT corn that is insect-resistant, the other for PNT potatoes that are insect-resistant;
- a 2002 follow-up on the 2000 corn audit; and
- the 2002 interviews with 14 growers of PNT corn that is insect-resistant, as well as sampling of field crops.

4.75 We found that the methodology used in the 2000 potato audit provided information about the compliance of both the proponents and growers. However, the methodology used in the 2000 corn audit comprised mainly interviews with proponents and reviews of documents, related to their education of growers and company sales staff about practices to prevent the development of insect resistance, and to their monitoring procedures. In 2002, the Agency interviewed 14 growers of insect-resistant corn and sampled field crops. Its report suggested that there was a lower compliance rate with conditions to prevent the development of insect resistance than was found in surveys conducted previously by the industry to monitor its own compliance. As a result, the Agency concluded that it is important to continue its own monitoring of growers.

4.76 The Agency told us that it plans a pilot project to sample the compliance of 100 corn growers, including sampling of field crops. In preparation, the Agency has provided training to its field inspectors on this new inspection activity. Involvement by corn growers will be voluntary because the Agency imposes conditions for insect resistance management on proponents, rather than on growers. However, due to the limited information on grower compliance obtained by the Agency to date, we concluded that its audits of conditions for unconfined release of corn have not yet enabled it to fully verify compliance with conditions imposed to prevent insect resistance from developing. In our opinion, assessing the compliance of growers is important for determining compliance with these conditions.

4.77 **Recommendation.** The Canadian Food Inspection Agency should complete its efforts to develop and implement a systematic approach for verifying compliance with conditions set for the unconfined release of insect-resistant plants with novel traits.

Agency's response. The Agency will continue to ensure that no authorization for an insect-resistant crop is being granted without a requirement for an insect resistance management plan and will continue to verify compliance by proponents with this condition. The Agency is a global leader in insect resistance management strategies and is internationally recognized for the work it has achieved in this area. The Agency recognizes the need to continue its efforts to evaluate compliance by growers with insect resistance management plans and it has already taken actions to further improve its ongoing compliance program.

4.78 **Recommendation.** The Canadian Food Inspection Agency should seek legal authority to enforce compliance by growers with conditions for unconfined release.

Agency's response. The Agency agrees with the recommendation. As noted in the report, the Agency currently has legislative authority to enforce compliance with the Seeds Regulations Part V by the seed companies. In addition, the Agency will explore options related to the authority necessary to enforce compliance by growers.

Approach for herbicide-tolerant crops under development

4.79 The Agency has taken a different approach regarding herbicide-tolerant PNTs. Use of herbicide-tolerant PNTs enables growers to spray fields with specified herbicides to destroy weeds without killing the crop. The Agency has worked with industry to develop approaches to stewardship of herbicide-tolerant crops. It has also recently decided to require proponents to have "herbicide tolerant crop stewardship plans" for new herbicide-tolerant PNTs. The Agency says that it is working with the industry to develop similar stewardship plans for herbicide-tolerant PNTs that have already been authorized. While proponents will have to submit these plans for Agency review and approval, unlike for insect-resistant PNTs, implementation of the plans will be voluntary. Further, the Agency told us that if the voluntary approach does not result in satisfactory management of herbicide-tolerant PNTs, it will make implementation of the plans mandatory. Therefore, in our opinion the Agency needs to ensure that these plans and any reports on their implementation are sufficiently detailed to enable it to assess whether this approach is resulting in satisfactory management of herbicide-tolerant PNTs.

4.80 **Recommendation.** The Canadian Food Inspection Agency should complete its efforts to develop, implement, and monitor the "herbicide tolerant crop stewardship plans" to ensure the approach is resulting in satisfactory management of herbicide-tolerant plants with novel traits.

Agency's response. The Agency concurs with the recommendation and will continue its efforts to implement herbicide tolerant crop stewardship plans. The Agency is recognized as a world leader in this regard and has already achieved significant co-operation with companies, grower groups, and the scientific community. The Agency will continue to build on its approach in order to ensure satisfactory management of herbicide-tolerant PNTs.

Regulatory framework

Regulatory framework needs to be clarified

4.81 We expected the Canadian Food Inspection Agency to have clear authority in its regulatory framework for its activities and decisions for regulating plants with novel traits (PNTs). While conducting our audit work we found a number of instances that suggest that the Agency should consider clarifying and strengthening the regulatory framework for PNTs.

4.82 Examples of areas where the regulatory framework for PNTs may need clarifying include the following:

- The Seeds Regulations Part V define unconfined release as being unrestricted release. However, they also give the Minister the authority to impose conditions upon unconfined release to manage environmental risks. The Agency may need to clarify that it has the authority to restrict unconfined release to certain geographical regions of Canada as it is currently doing for some PNTs.
- The Regulations provide authority to impose conditions on the proponents to manage environmental risks. Proponents in turn require growers to abide by some of these conditions. However, the Agency does not have the authority to enforce the conditions that proponents impose on growers.
- The Regulations provide very few tools to enforce the conditions imposed on proponents to protect the environment. The Agency can send warning letters, revoke authorizations for PNTs, or refuse to consider future applications: the latter two have very harsh consequences for proponents. The Agency has never refused to consider future applications, and states that it has never had cause to revoke an authorization for unconfined release.
- The government has recently instituted a policy of synchronizing authorizations for PNTs under the *Seeds Act*, the *Food and Drugs Act*, and the *Feeds Act*. This is to prevent contamination of the food or feed supply with unapproved PNTs. Its authority to synchronize decisions under these three acts is unclear.

4.83 **Recommendation.** The Canadian Food Inspection Agency should consider clarifying the regulatory framework for plants with novel traits to strengthen its ability to effectively deliver its regulatory program.

Agency's response. The Agency agrees with this recommendation and will explore avenues for clarifying the regulatory framework related to environmental release of PNTs. The Agency will also continue to update its regulatory directives. In 2002 and most recently in 2004, the Agency has taken steps to strengthen its directives in order to keep pace with emerging science and enhanced knowledge gained from experience with PNTs.

Confidential business information

Confidential business information is not being adequately protected

4.84 Proponents who seek authorization for confined and unconfined release of plants with novel traits provide information to the Canadian Food Inspection Agency that they identify as confidential business information. Proponents consider this information to be proprietary and commercially sensitive. Its unauthorized release or disclosure could affect the company's competitive position or its commercial interests. The Agency views this information as particularly sensitive, which if compromised, could lead to serious injury or economic loss to the company and cause serious embarrassment. This could potentially impair the Agency's ability to regulate plants with novel traits.

4.85 We expected the Plant Biosafety Office within the Agency to protect the confidential business information with appropriate security measures. This means that the Plant Biosafety Office should comply with the February 2002 Government Security Policy, the Agency's 1998 Security Policy, and the Agency's 1999 guidelines for employees and managers. We therefore examined the Plant Biosafety Office's compliance with these policies and guidelines.

4.86 At the time of our audit, we found that the Plant Biosafety Office was using some security measures to control access to the confidential business information. While the Plant Biosafety Office was taking its responsibilities to protect this information seriously, we found that it was not complying with important aspects of the Government Security Policy or the Agency's own security policy and guidelines. For example, the management of the Plant Biosafety Office had not formally assessed the sensitivity of the information under their control or the related threats and risks. This assessment is required to identify the measures needed to adequately protect this information. Further, the Plant Biosafety Office seldom designated (marked) the confidential business information it received from proponents or its own analyses of these data in accordance with Agency or government requirements. Moreover, we found that managers of the Plant Biosafety Office were unfamiliar with these key aspects of their security responsibilities. This was largely because they had not received any formal up-to-date training on security policies and procedures.

4.87 Our audit procedures were not designed to determine whether the confidential business information had been compromised, and no information came to our attention that it had been. However, the lack of compliance with important aspects of the Government Security Policy and the Agency's own security policy and guidelines led us to conclude that the Plant Biosafety Office was not adequately protecting the confidential business information provided by proponents or its own analyses of these data. However, once the Agency was made aware of our concerns, it began to take action to improve its security program.

4.88 **Recommendation.** The Canadian Food Inspection Agency should, within six months, formally review the Plant Biosafety Office's security practices and provide formal employee security training for all Plant Biosafety Office staff.

Agency's response. The Agency takes seriously its responsibility to protect confidential business information and no information has been presented that business information has been compromised. At the time of the audit, documents containing confidential business information were kept in a secure storage area, with restricted access, or in locked cabinets. Assessment information was recorded in a protected database, and stored on a separate server with restricted access. In addition the Agency has recently taken steps to enhance its security practices by more clearly identifying the classification of documents. Finally, the Agency is committed to conduct a formal review of security practices and take further actions, if warranted, and to provide additional training to the staff of the Plant Biosafety Office.

4.89 **Recommendation.** The Canadian Food Inspection Agency should, within one year, ensure that the Plant Biosafety Office's security practices comply with the Agency's security requirements, as well as those of the Government Security Policy.

Agency's response. The Agency agrees with this recommendation and is confident that, with the existing and enhanced security measures being implemented, it will fully comply with the Government Security Policy.

Conclusion

4.90 We examined whether the Canadian Food Inspection Agency's regulatory framework for plants with novel traits (PNTs) adheres to selected elements of government regulatory policy. We found weaknesses in the Agency's compliance with some key elements of the government's regulatory policy, and we concluded that there could be unassessed risks to the environment. We also had concerns about aspects of the regulatory framework for plants with novel traits. Specifically, we concluded that

- Because there is a risk that some imported PNTs may be escaping the regulatory process, the Agency is not administering the regulatory program for PNTs in such a way that achieves its environmental safety objectives.
- The Agency has not formally or systematically identified the risks that ornamental PNTs could pose to the environment. Our findings also suggest there is a risk that unapproved ornamental PNTs could be present in Canada.
- The Agency's audits of conditions for unconfined release of insect-resistant corn have not yet enabled it to fully verify compliance with conditions it imposes for the unconfined release of insect-resistant PNTs.
- The Agency may need to clarify some of the authorities the Seeds Regulations Part V confer on the Minister.

4.91 We examined whether the Agency's regulatory program for PNTs is managed and delivered in a manner that maintains quality and consistency. We concluded that the Agency has not adequately developed or implemented quality management procedures to ensure quality and consistency in its evaluations of applications for the unconfined release of PNTs.

4.92 Our final objective was to determine whether the Agency's program to regulate PNTs is managed in a transparent, fair, and accountable manner while protecting the confidential business information supplied by proponents. We concluded that

- The Agency was not adequately protecting the information supplied by proponents to the Plant Biosafety Office. Inadvertent disclosure of this information could potentially impair the Agency's ability to regulate PNTs.
- From our review of the documentation in the files, the Agency is not transparent in how it is implementing the Seeds Regulations Part V requirement to evaluate the long-term harmful effects on the environment before authorizing unconfined release of PNTs.

4.93 Our audit focussed on the processes that the Canadian Food Inspection Agency had in place to ensure that it was meeting its responsibilities with respect to the regulation of plants with novel traits. As such, our audit procedures were not designed to determine whether undeclared and undetected plants with novel traits were entering Canada, whether any unauthorized ornamental plants with novel traits were present in Canada, or whether the Agency had approved any plants with novel traits that should not have been; and no information came to our attention that any of these situations had occurred.

4.94 Nonetheless, our findings provide an early warning signal that some important aspects of the Agency's processes for regulating plants with novel traits need strengthening. Given that the next generation of plants with novel traits could pose new and more complex environmental risks, it is important that the Agency act on our recommendations if it is to be prepared to meet these future challenges.

About the Audit

Objectives

We had three audit objectives:

- To determine whether the Canadian Food Inspection Agency's regulatory framework for plants with novel traits (PNTs) adheres to selected elements of the government's regulatory policy.

  Government regulatory policy requires among other things that program activities support the achievement of the goals of the regulatory program and that government regulators reliably identify and manage risks. We also assessed whether the Canadian Food Inspection Agency had authority in its legislation or regulations for its PNT regulatory program activities and decisions.
- To determine whether the Agency's program to regulate PNTs is managed and delivered in a manner that maintains quality and consistency. Government regulatory policy requires that regulatory agencies develop and implement specifications and procedures to guide and control delivery of regulatory programs. It also requires that regulatory agencies document steps taken in decision-making processes.
- To determine whether the Agency's program to regulate PNTs is managed in a transparent, fair, and accountable manner while protecting the confidential business information supplied by proponents.

Scope and approach

Our audit focussed on the regulation of plants with novel traits (PNTs) by the Canadian Food Inspection Agency's Plant Biosafety Office. The Agency's legislation gives it the mandate to evaluate the environmental safety of PNTs before approving their release into the environment. We did not design the audit to enable us to conclude whether the Agency is adequately protecting the environment because we did not evaluate the quality of scientific data on which the Agency bases its evaluations, or the scientific rigour of the evaluations.

We conducted our work by

- interviewing Agency staff, managers, and selected stakeholders; and
- reviewing policies, procedures, and other documents as required; the Agency's electronic database; and selected case files. Note: We did not examine files and activities that occurred after 30 September 2003.

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Report of the Auditor General of Canada to the House of Commons—March 2004

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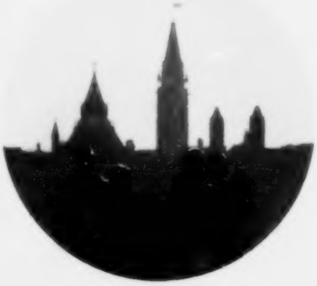
2004



Report of the
Auditor General of Canada
to the House of Commons

MARCH

Chapter 5
Canada Revenue Agency—
Audits of Small and Medium Enterprises

Office of the Auditor General of Canada

The March 2004 Report of the Auditor General of Canada comprises seven chapters, a Message from the Auditor General, and Main Points. The main table of contents is found at the end of this publication.

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Ce document est également disponible en français.

© Minister of Public Works and Government Services Canada 2004
Cat. No. FA1-2004/1-5E
ISBN 0-662-36245-4

Chapter

5

Canada Revenue Agency

Audits of Small and Medium Enterprises

All of the audit work in this chapter was conducted in accordance with the standards for assurance engagements set by the Canadian Institute of Chartered Accountants. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.

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Canada Revenue Agency
Audits of Small and Medium Enterprises

Main Points

5.1 The Canada Revenue Agency does not have the resources to be everywhere at once. It has to make trade-offs in deciding where to deploy resources to deal with competing threats to the tax base. To do this, it must ensure that all threats to the tax base are identified and considered in a consistent manner.

5.2 The Agency's aim is to improve compliance with tax legislation. However, it does not have the necessary information to enable it to measure compliance over time and, therefore, the effectiveness of its activities. For example, the Agency has not estimated the amount by which it overpays GST/HST refund claims. It is only now in the process of developing a compliance measurement framework.

5.3 The small and medium enterprise audit strategy could better reflect risk. Staffing in each tax services office for small and medium enterprise audits depends on the population of the different segments of taxpayers served by the office rather than the risk and complexity inherent in those taxpayers' affairs. To meet audit coverage targets, tax services offices can restrict up to 50 percent of their audits to one to three issues. These restricted audits take less time to complete but do not permit an overall evaluation of the taxpayer's compliance with tax laws. In addition, two studies conducted by the Agency found that 40 percent of all small and medium enterprises audited in a given year had little or no potential tax at risk according to the Agency's computerized risk evaluation system.

5.4 The Agency's own quality assurance reviews show that audits of small and medium enterprises need more rigour. We noted several areas where auditors must improve, such as using indirect methods of verification and considering the application of penalties more often.

Background and other observations

5.5 In December 2003, the government announced a major reorganization of some departments and agencies. The customs services operations of the Canada Customs and Revenue Agency were transferred to the newly created Canada Border Services Agency. The remaining organization operates as the Canada Revenue Agency.

5.6 The Agency defines small and medium enterprises as all self-employed individuals, small and medium-sized corporations, partnerships, and trusts. Small and medium enterprises include about 4.5 million taxpayers. Self-employed individuals accounted for almost 10 percent of the $90 billion in federal personal income tax revenue in 2003, while corporations with annual gross revenues of less than $15 million accounted for 36.5 percent of the $22 billion in federal corporate tax revenue that year. Over 60 percent of net goods and services tax (GST) and harmonized sales tax (HST) revenues, other than that collected by customs services on imported goods, comes from small and medium enterprises.

5.7 The small and medium enterprise sector is growing as the trend to self-employment increases. It is also the sector most at risk of participation in underground economy activities.

5.8 Computerized risk assessment systems, in conjunction with experienced auditors, are currently used to identify non-compliant taxpayers. Audits of taxpayers identified by the system as having high potential for non-compliance yield much higher reassessments than audits selected through other means.

5.9 The Agency has made changes to the computer-based risk criteria to select GST/HST refund claims for audit. In addition, it undertook several initiatives and pilot projects designed to strengthen GST/HST compliance. The validity of the risk criteria and the results of the new initiatives must now be measured.

5.10 The Agency has yet to complete a systematic review of the penalties provided in tax legislation to determine how effective these penalties are in improving compliance and achieving public confidence. We found that where the Agency reduced a certain penalty it applies to the late remittance of income taxes deducted from employee salaries by employers, it failed to get legislative authority to do so.

The Agency has responded. The Canada Revenue Agency agrees with all but one of our recommendations. In its responses, it provides background information and describes actions it will take to address the recommendations.

The Agency believes that one of our recommendations on better understanding compliance behaviour would divert resources from other activities and impose a burden on compliant taxpayers.

Introduction

5.11 In December 2003, the government announced a major reorganization of some departments and agencies. The customs services operations of the Canada Customs and Revenue Agency were transferred to the newly created Canada Border Services Agency. The remaining organization operates as the Canada Revenue Agency.

5.12 The majority of businesses in Canada fall into the small and medium enterprise category as defined by the Canada Revenue Agency. According to the Agency, this sector presents a higher-than-average risk of not complying with the requirements of the *Income Tax Act* and the *Excise Tax Act* when compared to other Canadian taxpayers, such as wage earners. As a result, we expect the Agency to have an appropriate compliance strategy for this sector, including an effective audit presence. The need for such a strategy is reinforced by an observation made in a study for the Department of Finance Canada's Technical Committee on Business Taxation about tax planning that occurs in small businesses:

> A prevalent attitude among small-business owners is that, given the risks and uncertainty that come with self-employment, they are entitled to organize their affairs to pay less tax than someone who enjoys the comfort of a regular salary.

Did you know?

- Federal personal income tax revenue in 2003: **$90 billion**

  Percentage of that amount accounted for by the self-employed: **almost 10%**
- Federal corporate tax revenue in 2003: **$22 billion**

  Percentage of that amount accounted for by corporations with annual gross revenues of less than $15 million: **36.5%**
- Net GST/HST revenue (other than that collected by Customs on imported goods) in 2003: **$14 billion**

  Percentage of that amount attributable to small and medium enterprises: **over 60%**

5.13 The Agency defines all self-employed individuals, small and medium-sized corporations, partnerships, and trusts as small and medium enterprises. Small corporations include those with annual reported revenues of less than $1 million. Medium corporations have annual reported revenues not exceeding $250 million. The Agency estimates there are about 4.5 million small and medium enterprises in Canada.

5.14 The small and medium enterprise sector grows as the trend to self-employment increases. It is also the sector most at risk of participation in underground economy activities. In our April 1999 Report, Chapter 2, Revenue Canada—Underground Economy Initiative, we noted that the underground economy results in tax evasion and represents an estimated annual loss of federal and provincial tax revenues of $12 billion. Promoting compliance with tax legislation in such a large and diversified group of taxpayers is a challenge for the Agency.

The small and medium enterprise compliance strategy

5.15 The Agency seeks to promote compliance with tax legislation through communication, quality service, and responsible enforcement. As a result of its activities it expects that Canadians will pay the amount of tax properly owed under the law and that the tax base will be protected. To succeed, the Agency knows that it must use different methods to effectively target and address compliance issues.

5.16 In April 2001, the Agency launched an exercise to identify the elements that must be in place to ensure good performance in the future. This initiative resulted in a series of Future Directions reports aimed at different groups of taxpayers. For small and medium enterprises, the Agency identified increasing its outreach, expanding electronic services, improving the accuracy of its processing activities, and ensuring compliance.

5.17 In particular, it committed to the precise targeting of enforcement actions: focussing efforts on non-compliant taxpayers; quickly identifying complex cases of non-compliance; and then assigning those to specifically established units. The Agency also committed to contacting new enterprises to provide timely guidance and assistance and providing for more on-line filing of information returns and for secure Web access by taxpayers to their account information.

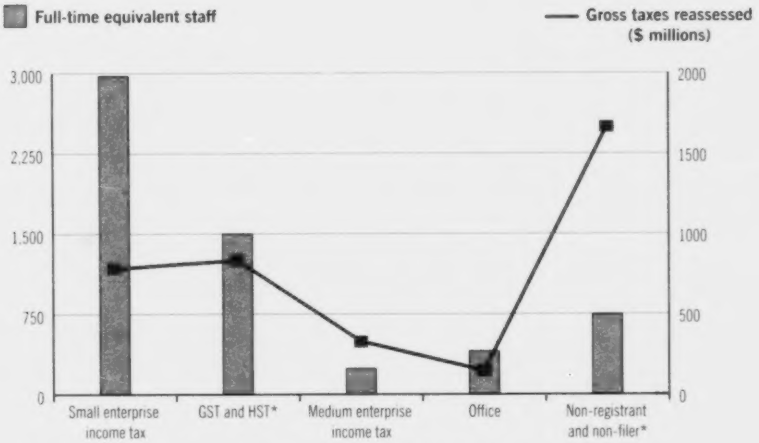
The small and medium enterprise audit program

Goods and services tax (GST)—The tax on most goods and services consumed in Canada that became effective 1 January 1991. Basic groceries, residential rents, and most health and educational services are exempt.

Harmonized sales tax (HST)—The single tax that replaced the GST and provincial sales tax in Nova Scotia, New Brunswick, and Newfoundland and Labrador on 1 April 1997.

5.18 The small and medium enterprise audit program is one component of the Agency's overall compliance strategy. Its mandate is to promote compliance with the *Income Tax Act*, *Excise Act*, and *Excise Tax Act* in small and medium enterprises. The Audit Directorate within the Compliance Programs Branch is responsible for this program. The small and medium enterprise audit program has the largest staff of all audit programs and is divided into units that focus on different-sized businesses and different taxes (Exhibit 5.1). The Assessment and Collections Branch is responsible for identifying and following up on enterprises that have not filed their tax returns or registered to collect the goods and services tax (GST) or the harmonized sales tax (HST).

Exhibit 5.1 The small and medium enterprise audit program, 2002-03



*This component includes small and medium enterprises and other taxpayers.

Source: Canada Revenue Agency

5.19 Auditors and program officers carry out audits and other compliance activities in 44 tax services offices across the country. Headquarters personnel in Ottawa, with the support of six regional offices, provide program direction and administrative guidelines to the tax services offices. Within the

Compliance Programs Branch, the Compliance Research and Business Management Directorate provides compliance research and risk assessment services to support the small and medium enterprise audit program.

5.20 Audits of income tax returns and GST/HST returns are combined for individuals reporting revenues of less than $800,000. For other individuals and all corporations, auditors who specialize in either type of tax perform separate audits, although the audits may happen concurrently.

5.21 The GST is administered in Quebec by the ministère du Revenu (Department of Revenue) under the guidance of a master agreement between the Government of Canada and the Government of Quebec dated 1 July 1992. More than a dozen subsidiary agreements outline terms and conditions covering different aspects of tax administration. New terms and conditions for carrying out audit activities took effect 8 August 2002. They call for the ministère to follow the Agency's policies, procedures, standards, and practices when it audits files. They also establish the process by which the Agency and the ministère are to co-ordinate their annual audit strategy.

Focus of the audit

5.22 The objectives of the audit were to assess how well the Agency

- understands the compliance behaviour of all taxpayers and allocates resources based on an integrated view of the risks to the tax base,
- allocates the resources available for audits of small and medium enterprises based on the risk of non-compliance,
- designs and implements audit activities to address non-compliance in small and medium enterprises, and
- measures the results of its activities.

5.23 Although we covered all components of the small and medium enterprise audit program, we placed emphasis on those dealing with small enterprise income tax audits and GST/HST audits. Those components employ over 75 percent of the audit program staff and are responsible for more than 99 percent of the small and medium enterprises in Canada. Further information about the audit objectives, scope, approach, and criteria can be found at the end of the chapter in **About the Audit**.

Observations and Recommendations

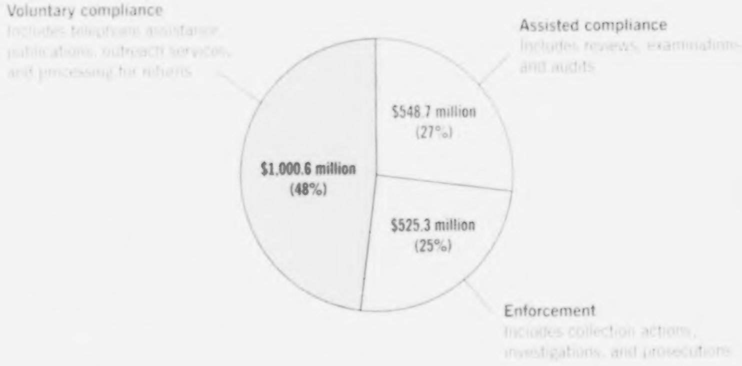
Risk management

5.24 **Compliance activities.** To know where to allocate its compliance resources, including how much to assign to small and medium enterprise audits, the Canada Revenue Agency needs to have an overall view of the threats to the tax base and to know which compliance activity is most effective under what circumstances. It also needs a rational process to allocate resources to a variety of compliance activities.

5.25 Non-compliance with tax legislation can take the form of failing to file a tax return or register to collect the GST/HST, incorrectly reporting income or deductions, or failing to remit taxes owing. These are the risks to the tax base. They result from a variety of reasons: taxpayers may not know their obligations or understand parts of the *Income Tax Act* and *Excise Tax Act*; they may not interpret the law as intended; they may wilfully evade tax; or they may make mistakes on their returns. Reasons for non-compliance vary from one taxpayer to another and among taxpayers of different types, industry sectors, and revenue levels.

5.26 The Agency carries out a mix of education, facilitation, processing, audit, and enforcement activities to improve taxpayer compliance. It also suggests changes to legislation to the Department of Finance. Penalties also play a role in encouraging compliance. In its annual performance report, the Agency groups these activities in three broad categories—voluntary compliance, assisted compliance, and enforcement—and shows the proportion of resources allocated to each (Exhibit 5.2). The cost of compliance activities increases as they move toward the enforcement end of the spectrum. Audits, for example, are an expensive way of gaining taxpayer compliance.

Exhibit 5.2 Compliance activities and their cost, 2002-03



Source: Canada Revenue Agency

Risk management needs to be improved

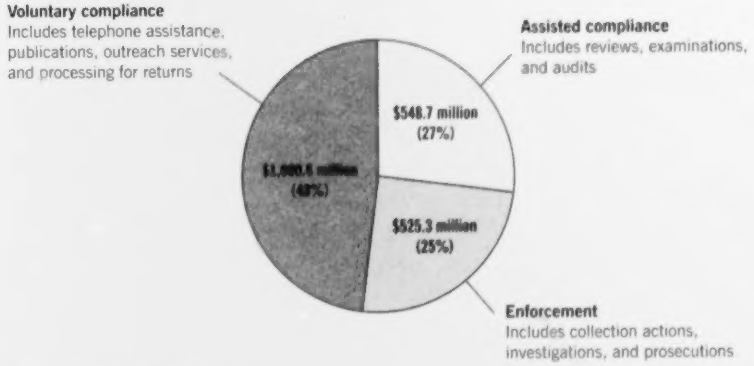
5.27 The Compliance Research and Business Management Directorate of the Compliance Programs Branch is the focal point in the Agency for understanding compliance and assessing the risks of non-compliance. However, many areas within the Agency research compliance behaviour, sometimes in partnership with the Directorate and sometimes in isolation.

5.28 These areas then develop compliance strategies based on their view of the risk in their particular area. But compliance activities should be designed with an integrated view of risks. Informed decisions could then be made as to how many resources should be devoted to, for example, examining disability tax credit claims, GST/HST refund claims, and requirements for employers to withhold income tax, as compared to developing and running awareness campaigns or providing seminars for new business owners, and so on.

or deductions, or failing to remit taxes owing. These are the risks to the tax base. They result from a variety of reasons: taxpayers may not know their obligations or understand parts of the *Income Tax Act* and *Excise Tax Act*; they may not interpret the law as intended; they may wilfully evade tax; or they may make mistakes on their returns. Reasons for non-compliance vary from one taxpayer to another and among taxpayers of different types, industry sectors, and revenue levels.

5.26 The Agency carries out a mix of education, facilitation, processing, audit, and enforcement activities to improve taxpayer compliance. It also suggests changes to legislation to the Department of Finance. Penalties also play a role in encouraging compliance. In its annual performance report, the Agency groups these activities in three broad categories—voluntary compliance, assisted compliance, and enforcement—and shows the proportion of resources allocated to each (Exhibit 5.2). The cost of compliance activities increases as they move toward the enforcement end of the spectrum. Audits, for example, are an expensive way of gaining taxpayer compliance.

Exhibit 5.2 Compliance activities and their cost, 2002-03



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5.29 The Agency does not have the resources to be everywhere at once. It has to make trade-offs in deciding where to deploy resources to deal with competing threats to the tax base. It must assess the various risks to the tax base and it must know the cost of its intervention and the costs its intervention imposes on taxpayers. The Agency was unable to provide us with an overall risk analysis to support its current resource allocation.

Comprehensive information about risks to tax base needed

5.30 The Compliance Research and Business Management Directorate is developing a compliance measurement framework. This is a major initiative. The Agency sees the framework as the foundation for the study of compliance. Plans are for the framework to lay out the key concepts, constructs, and operational definitions that will guide compliance research planning, monitoring, and reporting. The Directorate also plans to integrate compliance results from relevant work done by all areas within the Agency and from research done outside the Agency.

5.31 As part of the framework, the Directorate is developing a compliance measurement information system to collect and manage data on measures that the Agency believes show compliance. However, it is too early to determine whether the compliance measurement framework and related system will produce the comprehensive information on compliance needed for the strategic management of tax programs within the Agency, or whether it will help provide key measures of compliance to determine the Agency's overall effectiveness in improving compliance.

5.32 **Recommendation.** The Canada Revenue Agency should ensure that all threats to the tax base are identified and considered in a consistent manner to support its allocation of available resources. It should consider implementing an overall risk management function or responsibility centre for risk management to achieve this.

Agency's response: The Canada Revenue Agency fully recognizes the importance of identifying and considering threats to the tax base in a consistent manner when allocating available resources. Accordingly, we agree that it is necessary to periodically validate and refresh information on compliance risk for informed decision making.

The Agency has an overall tax compliance risk management process founded on the following key elements: identifying non-compliance and distinguishing compliant taxpayers from those who are non-compliant; understanding factors that drive or enable non-compliance; prioritizing compliance issues based on risk assessment; developing targeted approaches that focus on the underlying drivers of non-compliance and that maintain existing compliance; leveraging strategic partnerships; and measuring success in increasing compliance and refining our approaches through continuous learning.

The Office of the Auditor General notes that the Agency is developing a compliance measurement framework and recognizes that this is a major initiative. Once fully developed, this framework will allow us to monitor general trends in compliance and to study the effectiveness of an individual program or compliance initiative. The Agency is also undertaking a comprehensive review of its tax collection methodology. This review will examine the approach to risk management across the Agency from a program, cross-functional, and strategic perspective. The review will also examine other factors, in addition to risk, which guide the allocation of resources.

The outcome of these initiatives will assist the Agency in enhancing its overall risk management and compliance strategy development. It will also be considered in future deliberations on the merits of implementing a single responsibility centre for risk management.

Information on compliance

5.33 The Agency recognizes in its performance report that understanding compliance behaviour helps to

- determine the right mix of compliance activities,
- provide a benchmark against which the Agency can measure the effectiveness of its activities to promote voluntary compliance, and
- identify taxpayers who present a higher risk of non-compliance.

Audit coverage rates lack support

5.34 In 2001, the Treasury Board of Canada Secretariat completed a resource and management review of the Canada Customs and Revenue Agency. The Secretariat noted that the Agency had established what it considered to be optimum coverage rates for audit activities, informed by compliance research conducted by the Agency and experience, and concluded that additional audit resources would generate additional tax revenues. We agree that additional audit resources are likely to generate additional revenue. However, Agency officials could not provide us with a definition of an optimum rate of audit coverage and evidence to support that they have determined it.

5.35 As a result of the resource and management review, the Agency received funding to increase audit staff by up to 1,860 employees. These increases are for all audit programs, including small and medium enterprise audits, and are to be implemented over five years. The new funding was conditional on the Agency achieving increased audit coverage and generating additional tax revenues. The Agency determined audit coverage targets over those five years on the basis of a planned staff complement for several program components. Exhibit 5.3 shows the targeted audit coverage in 2005–06 and the estimated coverage for 2000–01 and 2002–03 for the small and medium enterprise audit program.

5.36 As a result of the additional resources, the Agency expected gross tax revenue to increase by $3.2 billion over five years. The Agency did not break down the increase by audit program. As a result, the small and medium enterprise audit program has specific audit coverage targets but no corresponding revenue targets.

Exhibit 5.3 Estimated and expected audit coverage for the small and medium enterprise audit program

Audit program	Estimated taxpayer/ registrant population	Audit coverage (as a percentage of population)		
		Estimated 2000-01	Estimated 2002-03	Targeted 2005-06
Small enterprise income tax (individuals)	2,820,000	0.68	1.01	1.16
Small enterprise income tax (corporations)	1,318,000	0.87	0.99	1.26
GST/HST	2,161,000	0.80	1.04	1.38
Medium enterprise income tax	5,500	12.00	21.80	20.80

Source: Canada Revenue Agency

The Core Audit Program has not produced desired results

5.37 The Audit Directorate of the Compliance Programs Branch also researches compliance. One of its major initiatives in collaboration with the Compliance Research and Business Management Directorate is the Core Audit Program. This program, begun in 1999, seeks to determine the degree of non-compliance in a given population of small and medium enterprise taxpayers as well as the nature and cause of that non-compliance. It does this by auditing a sample of taxpayers or registrants chosen at random. Results of randomly selected audits can provide compliance information not available through regular audits selected on some basis of risk.

5.38 Because of resource considerations, the Core Audit Program has focussed on segments of the small and medium enterprise population or on a specific tax or category of taxpayer each year. To compare the compliance behaviour of individual and corporate taxpayers and GST/HST registrants in different industry sectors and over time, the Agency needs a detailed, long-range plan to guide its Core Audit Program. Currently it has not identified, beyond next year, the specific segment of the population the program will cover.

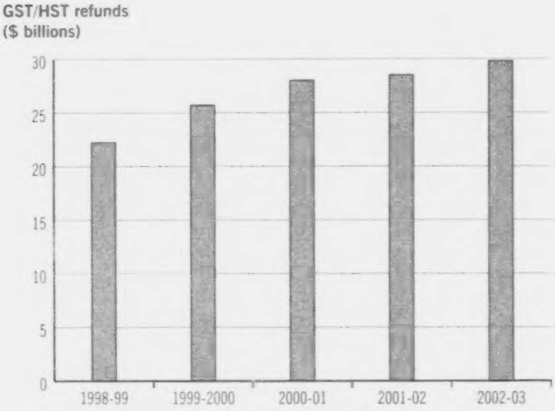
5.39 The Agency did not complete its analysis of the 1999 Core Audit Program, which covered audits of tax and GST/HST returns from 1996 to 1999, until the summer of 2003. The analysis of subsequent years' results has not begun. The Agency told us that problems with capturing data, completing audits, and developing an acceptable definition of what constitutes non-compliance contributed to delays in analyzing and reporting results. The Agency suspended the Core Audit Program for the current fiscal year to allow officials to make corrections and take stock.

Overstatement of GST/HST refund claims has not been estimated

5.40 The Agency needs to know, among other things, how much revenue is likely at risk for each type of non-compliance so that it can determine an appropriate strategy to minimize the loss. Overpayments of GST/HST refunds are one example: for a variety of reasons, some registrants claim bigger refunds than those to which they are entitled. They might misunderstand the tax rules, make clerical and system errors, or willfully intend to deceive.

5.41 In 2002–03, the Agency received 2.6 million GST/HST refund claims on which it paid out $29.8 billion. It audited 1.6 percent of these claims before paying them and found $247 million in overstated claims. The Agency has not estimated the potential overstatement in the 98.4 percent of claims that have been subjected to a risk assessment process but that have not been audited. Exhibit 5.4 shows GST/HST refunds paid by the Agency in the last five years.

Exhibit 5.4 GST/HST refunds paid in the last five years



Source: Public Accounts of Canada and Canada Revenue Agency

5.42 Of the 1.6 percent (or 42,000) of refund claims audited in 2002–03, 262 were chosen with some degree of randomness from the 1.5 million claims identified by the Agency as presenting little or no risk of error. The audits of the 262 refund claims found that 42 of these were overstated by a total of about $1 million. The Agency audits claims selected with some degree of randomness to gain insights into the behaviour of registrants and verify how well the audit selection system works. The Agency could modify the selection process for these types of audits to a proper statistical basis and develop a comprehensive sampling plan with a suitable sample size, so that good statistical projections of the amount of overstated claims could be made.

Information on completed audits lacking

5.43 The Agency also needs better information on audit results in order to understand non-compliance. Currently, the Audit Information Management System captures a variety of information on audits, such as the reason for selecting the audit, the section of an act that was not complied with, and whether the auditor completed a full or restricted audit. However, capturing additional information, such as the reason for the audit adjustment and the auditor's judgment of the nature and cause of the non-compliance, would increase understanding of non-compliance. In addition, comparing the estimate of someone's potential tax at risk against actual audit results—as soon as the audit is completed—would help to quickly validate the system that produces that estimate.

Potential tax at risk—The difference between how much income tax and GST/HST a person or corporation reports they should be paying and what the Agency estimates those amounts should be. The Agency uses a series of criteria and other information to arrive at its estimate.

5.44 Recommendation. To better understand the compliance behaviour of small and medium enterprises and thus determine the right mix of compliance activities, the Canada Revenue Agency should do the following:

- strengthen the Core Audit Program by developing a multi-year plan to cover specific segments of the population, and set deadlines for the completion of the audit work and the analysis of results;
- develop statistically valid estimates of the probable value of overstatements of GST/HST refund claims to develop a compliance strategy to minimize the overpayments; and
- capture additional information on audit results and analyze that information to gather additional insights into taxpayer behaviour, reasons for non-compliance, and methods of detection.

Agency's response: The Agency concurs with the recommendation to develop a multi-year plan and set deadlines for the completion of the Core Audit Program's work and the analysis of the results. Steps have also been taken to improve the integrity of the data collected.

The Agency recognizes the vital importance of identifying risks to the tax base and of developing effective strategies. For example, it has a GST/HST compliance strategy that provides service and support to those who wish to comply with the law, while taking responsible enforcement actions to identify and deal with cases of non-compliance. As recognized by the Office of the Auditor General, the Agency has implemented various risk assessment processes to evaluate the validity of refund claims before they are paid. These processes will be tested and reviewed for improvements on an ongoing basis.

A range of measurement methods can be used to quantify compliance. It is internationally recognized that all methods have specific benefits, limitations, and utility. The development of statistically valid estimates of the overstatement of refund claims would require the diversion of significant resources from other compliance activities and the imposition of burden on compliant taxpayers.

The Agency agrees with the need to better understand the compliance behaviour of small and medium enterprises and will continue to utilize a variety of methodologies to identify compliance risks and to assess the effectiveness of its compliance programs. These include monitoring tax data relative to indicators of socio-economic change, analyzing program data and results to identify compliance trends and risk factors, conducting random sample reviews to measure non-compliance in specific areas, evaluating the achievement of our programs to ensure that their objectives are being achieved, and conducting surveys to obtain the public's views on compliance. The Agency will also continue to carefully review studies undertaken by the academic community and work by other tax administrations to further inform our understanding of the compliance challenges facing tax administration.

The Agency agrees that additional information on audit results would be beneficial and we have identified possible improvements to the current information reporting systems. Two major projects have been initiated to improve the availability, consistency, and reliability of data, including capturing non-compliance information to refine our risk-profiling capability and better target compliance actions.

While additional information from audit results is useful for understanding reasons for non-compliance and methods for detection, it provides limited insight into taxpayer behaviour. Accordingly, the Agency also uses public opinion research to contribute to its understanding of the psychology of tax compliance and the factors affecting taxpayer behaviour.

Risk evaluation

5.45 Focussed audits directly reduce the burden on compliant businesses and try to ensure that the same rules apply to all. The key element of a focussed audit program is targeting areas of high risk. This involves identifying high-risk sectors and selecting high-risk taxpayers within these sectors. The Agency has several systems designed to assess the risk of non-compliance in the small and medium enterprise population.

The Computer Assisted Audit Selection System is useful

5.46 The Computer Assisted Audit Selection System evaluates the risk of non-compliance in individual, corporate, and GST/HST returns. For each income tax return filed and for each GST/HST registrant, the System calculates the amount of potential tax at risk. The System then classifies taxpayers as a low, moderate, or high risk for non-compliance and highlights potential areas of non-compliance. Studies completed by the Compliance Research and Business Management Directorate to validate and improve the System's results show a positive relationship between its estimate of tax at risk and actual tax reassessed when a taxpayer is audited. These studies also conclude that there is still a need for an experienced auditor's judgment in assessing the risk of non-compliance in any particular file.

5.47 Currently, the System estimates the tax at risk for each separate income tax and GST/HST return filed. That means that returns filed by members of groups that are not operating at arm's length are viewed separately. And, instead of estimating tax at risk for the whole group, when the potential tax at risk may well be greater than the sum of each return, the System makes individual estimates. In addition, the Agency is not applying the tax-at-risk calculation to large partnerships and trusts.

Validation required for criteria used to select GST/HST refund claims for review

5.48 Before paying a GST/HST refund claim, an automated processing system evaluates each return against a series of risk criteria. About 60 percent of refund claims pass all the selection criteria and are paid automatically. The other 40 percent, which account for about 70 percent of the dollar value of the refund claims received by the Agency, go to tax services offices for further appraisal. Available resources in the tax services offices allow 4 percent of the claims referred, or 1.6 percent of all claims submitted, to be audited.

5.49 Currently, the risk criteria used to refer refund claims to tax services offices result in many offices receiving a lot more claims than they can handle. A study by the Agency found that the number of referrals to tax services offices was unmanageable. Because auditors must review a large number of refund claims, they review each claim more quickly, thereby increasing the possibility of approving an unsupported or fraudulent return without doing an audit.

5.50 The Agency uses the amount being claimed as one of the risk criterion. It is the criterion responsible for most of the referrals of claims to tax services offices. Headquarters' staff has encouraged tax services offices to consistently set and maintain acceptable claim amount limits for each registrant. Despite this, the number of claims referred to tax services offices remains high.

5.51 The Agency has made changes to the risk criteria in the last two years in an attempt to make them more discriminating. The Agency intends to evaluate the current risk criteria. The effectiveness of the GST/HST System's selection criteria and of the screening activities in the taxation services offices can be measured by how often audits result in a change to the amount claimed. In 2002–03, auditors changed the amount claimed in 56 percent of the refund claims audited. In 2001–02, that amount was 55 percent.

5.52 In the last two years, special teams in each region and in selected taxation centres have also begun developing profiles of potentially fraudulent GST/HST registrants and following up on what they consider high-risk enterprises to try to identify fraudulent GST/HST refund claims before they are paid. The Agency has not yet measured the effectiveness of these activities.

5.53 The Agency has recently strengthened one of its procedures to deal with GST/HST refund claims. In the past, when a registrant could not be contacted or failed to respond to an auditor's request for information to support a claim, the auditor would simply deny the refund. Unscrupulous individuals could quickly realize that few refund claims were audited and, if selected for audit, they could abandon their claim with no consequences. New procedures require tax services offices to follow up on registrants who fail to contact the Agency when requested to do so. Agency officials have yet to measure the effectiveness of the new procedure.

5.54 In March 2003, the House of Commons Standing Committee on Public Accounts held hearings on GST/HST fraud and the reporting of losses of public money and property. The Committee's report contained five recommendations. Among them: the Agency should inform the Committee of recent initiatives and pilot projects designed to strengthen GST/HST compliance and enforcement activities. In response, the Agency described several activities but did not provide information on how it plans to measure the results of those activities.

5.55 **Recommendation.** The Canada Revenue Agency should improve its systems to identify non-compliant small and medium enterprise taxpayers. In particular, the Agency should

- improve the Computer Assisted Audit Selection System by linking returns of taxpayer groups that do not operate at arm's length for the purpose of determining potential tax at risk and adding information to enable the calculation of income tax at risk for trusts and large partnerships, and
- undertake regular studies to validate the effectiveness of computer-based and manual risk evaluation systems.

Agency's response: The Agency's Computer Assisted Audit Selection System currently links non-arm's length returns (for example, corporations and their controlled companies, and corporations and their shareholders). The Agency agrees to evaluate linking trusts and large partnerships in risk assessment processes, and evaluate assessing the risks of related groups.

The Agency recognizes the importance of undertaking regular studies to validate the effectiveness of computer-based and manual risk evaluation systems. Regular studies that measure the effectiveness of the Computer Assisted Audit Selection System and other initiatives are already performed, and will continue. The studies include analyzing anomalies in individual cases, modelling new criteria for identifying non-compliance, validating and refining existing criteria, and integrating new sources of data into the risk assessment systems.

Design and delivery of audit activities

Staffing of tax services offices could better reflect risk

5.56 With a few exceptions, the number of auditors assigned to a tax services office is proportional to the number of the different types of taxpayers served by that office. In that way, in all areas of the country, taxpayers within a given segment have an equal chance of being audited. However, information in the Computer Assisted Audit Selection System indicates that the average potential tax at risk is different in different regions. Some tax services offices must deal with taxpayers who generally present a higher risk of non-compliance, yet those offices have no more auditors than those where taxpayers appear more compliant.

5.57 As well, the Agency has little information on the complexity of taxpayers' returns. It estimates the time and the experience level of the auditor needed to complete an audit based on the gross revenues reported by the taxpayer. However, the complexity and the risks inherent in a taxpayer's return, rather than the revenue level, increase the time needed and the level of experience required to do the audit. There is a danger that, in areas of the country where there is more risk and complexity, auditors will audit a smaller percentage of risky and complex files.

5.58 **Recommendation.** The Canada Revenue Agency should study the possibility of assigning complexity ratings to small and medium enterprise files and of allocating audit resources to tax services offices to reflect the profiles of their files and their tax-at-risk estimates.

Agency's response: The Agency agrees that complexity ratings and tax at risk are important elements in allocating audit resources. Its risk assessment system permits the identification of tax compliance risks for all individuals, businesses, and GST/HST registrants who file income tax and GST/HST returns.

The majority of our audits are focussed on files with the highest risk of non-compliance. We also consider other important factors in allocating resources. These factors include maintaining a credible audit presence and high visibility throughout the country, meeting commitments to the provinces and territories to protect their portion of tax revenues, and providing service and support to those who wish to comply while taking enforcement actions to identify and deal with cases of non-compliance.

The Agency's current allocation process involves, among other things, segmenting the self-employed and business population along various lines, including type of tax (income and GST/HST), structure (individual and corporate), and size of entity. Within a given segment stratified by gross revenue range, and within the attributes related to that segment, the allocation is based on the population of that segment. For small and medium enterprises, the Agency's view is that segmentation by revenue ranges provides a fair, if not perfect, proxy for complexity at reasonable cost. Notwithstanding, the previously mentioned studies on a compliance measurement framework and tax collection methodologies will assist the Agency in enhancing its overall risk management and allocation of resources.

Meeting coverage rates drives audit activities

5.59 The strategy of the small and medium enterprise audit program is to audit high-risk taxpayers and to maintain selected levels of audit coverage for different groups of taxpayers. These are competing priorities because, as mentioned earlier, auditing the returns of high-risk taxpayers is generally more complex and takes longer to perform. Therefore, an office that performs a greater proportion of high-risk audits can perform fewer audits overall.

5.60 Currently, the Agency is putting emphasis on meeting the coverage targets agreed to with the Treasury Board Secretariat as a condition for additional funding. To meet these targets, tax services offices plan a mix of full compliance audits and restricted audits. Restricted audits focus on one to three issues and their design does not permit auditors to make an overall evaluation of the taxpayer's compliance with tax laws. Because full compliance audits take more time to complete than restricted audits, increasing the percentage of restricted audits increases audit coverage. National guidelines state that up to 50 percent of audits carried out in a tax services office can be restricted. To meet coverage rates, auditors may pass over taxpayers presenting greater potential tax at risk for taxpayers presenting a risk of non-compliance in a specific area—such as claiming higher than average expenses of one category or another. Despite the 50 percent limit placed on restricted audits, several taxation services offices exceeded this limit.

5.61 The Compliance Research and Business Management Directorate conducted two studies of audit results of individual tax returns for 2000 and corporate tax returns for 1997. The studies showed that the chance of a taxpayer being audited increased as the estimate of potential tax at risk increased. In fact, individual and corporate tax returns in the highest tax-at-risk ranges were 10 times more likely to have been audited than tax returns in the no-risk category.

5.62 Still, the studies noted that 40 percent of all taxpayers audited were identified by the Computer Assisted Audit Selection System as having little or no potential tax at risk. These audits of tax returns were initiated as a result of leads, taxpayer-requested adjustments, or special audit initiatives. On average, the studies show that when the results were subsequently compared to reassessments of higher-risk files, as identified by the System, they were three to four times lower. While the studies concluded that increased audits of taxpayers with a higher potential tax at risk would increase tax recoveries, the Agency believes that it needs to address these other workloads to achieve overall compliance with tax laws.

5.63 Discussions with audit section managers and team leaders in tax services offices across the country confirmed the importance that they place on meeting annual audit coverage targets set for their offices and regions. Team leaders evaluate auditors on their performance in relation to audit plans, audit tests, technical issues, quality of correspondence and reports, professionalism, and timeliness. In assessing an auditor's performance, substantial weight is also given to whether the auditor has completed the expected number of audits.

Audits need more rigour

5.64 **Quality assurance reviews.** The Agency has conducted national quality assurance reviews of the small and medium enterprise audit program to ensure that the audit work meets a national standard of quality. Experienced auditors examine audit files in tax services offices across the country and rate them against a number of criteria.

5.65 We looked at a cross-section of quality assurance reviews conducted in the last three years to see whether audits were meeting the Agency's quality standards. Specifically, we focussed on areas where, as a result of discussions with audit team leaders, we felt auditors might not be meeting those standards partly due to their desire to meet production targets. We looked at 16 quality assurance reports covering 891 small and medium enterprise audits performed by auditors in tax services offices across the country. Some of the findings merit further review.

5.66 **Lack of audit plans.** There were no written audit plans for 33 percent of the audits reviewed. With the focus on the ongoing evaluation of risk, a plan is essential to document the potential areas of risk that caused an auditor to select a particular file and the planned procedures to address those risks. As the audit unfolds and the initial evaluation of risk is confirmed, amplified, or refuted, there is a clear basis from which to modify audit procedures.

5.67 **Compliance reviews.** National guidelines require that auditors conducting audits of income tax or GST/HST complete a brief review of that taxpayer's compliance with the other tax. These are called compliance reviews. They are required because, except for the smallest taxpayers, auditors who specialize in only one of the taxes perform either income tax or GST/HST audits. Performing compliance reviews is one way the Agency is trying to more efficiently audit both taxes while minimizing disruption to the taxpayer. The quality assurance results show compliance reviews missing in 38 percent of the audits that should have had them.

5.68 **Indirect methods of verifying income.** Auditing small enterprises requires special techniques because they often lack the sophisticated internal controls on which auditors can rely to evaluate the accuracy of amounts reported. This is particularly true in industry sectors where cash transactions are common. To conduct a thorough audit, national guidelines instruct auditors to use indirect methods of income verification, including a technique called net worth audits. The quality assurance reviews found that auditors had not used net worth or other indirect methods of income verification in 55 percent of the audits that merited them.

5.69 Team leaders in many tax services offices told us that using indirect verification techniques takes time. They said that a net worth audit takes from 150 to 300 hours and that spending that much time on an audit would prevent them from meeting their coverage targets. In some tax services offices, team leaders cited lack of training as a reason for their auditors not using indirect methods of verification. Headquarters staff told us that a new comprehensive course on indirect methods of verification soon would be offered to auditors in the taxation services offices. Still, this will not address the issue that these audits take time.

5.70 **Penalties not always considered.** Finally, the quality assurance reports we reviewed found that auditors failed to consider the application of gross negligence penalties in 54 percent of the audits where such penalties may have been warranted.

5.71 **Recommendation.** The Canada Revenue Agency should

- assess its current policy of having up to 50 percent of small and medium enterprise audits restricted to between one and three specific issues,
- ensure that its quality standards for carrying out audits are met, and
- review auditors' performance criteria to ensure that they give appropriate weight to quality standards as well as the completion of a reasonable requisite number of audits.

Agency's response: The Agency agrees to review the frequency and the circumstances in which it uses restricted audits to achieve compliance to determine whether the current policy of up to 50 percent restricted audits is too high or too low.

Restricted audits play a key role in increasing the Agency's visibility through increased coverage levels. This, in turn, enables it to maintain an audit presence throughout the country that is fundamental to its underlying compliance strategy.

Auditors continually conduct a risk assessment of files throughout the course of audits and tailor audit plans accordingly. Consequently, most audits are restricted to some degree. More comprehensive audits are undertaken in cases where serious non-compliance is encountered.

The Agency is committed to the conduct of high quality audits and has several measures in place to assess quality. Team leaders are responsible for ensuring that national standards of quality are achieved in every file. Technical advisors ensure that all issues are identified and assessed in a technically accurate manner.

The Agency's Quality Assurance program contributes to the attainment of high standards of quality outputs through quality assurance reviews. Quality Assurance plays a key role in identifying training needs and the application of best practices. Program-monitoring visits are regularly conducted by headquarters' staff to ensure that program policies and guidelines are being followed on a consistent basis. The Agency will continue to ensure that quality standards for carrying out audits are achieved.

The Agency has performance criteria for auditors that encompass quality standards as well as the completion of a reasonable number of audits. We agree to continue to review the current performance criteria and to emphasize the importance of using a full range of qualitative standards in reviewing an auditor's performance.

Legislated penalties

5.72 Tax legislation provides for penalties in cases of non-compliance. The Agency views a graduated penalty structure as a key component of a fair system that promotes compliance. In 2001, it planned to consult with Finance Canada to ensure that the penalty structure properly recognized prior good performance and imposed more severe penalties for systematic evasion and non-compliance.

5.73 The Agency told us that, as a result of preliminary discussions with Finance Canada, a decision was made not to review the income tax penalty structure at this time, with one exception. In July 2003, the Agency revised the penalty for all instances of late remittance of source deductions from 10 percent of the amount of the late remittance to a range of 3 percent to 10 percent, depending on how late the remittance is. While our audit did not set out to look at the Agency's compliance program that deals with source deductions, we found that the Agency lacks the legislative authority to implement the reduced penalty.

5.74 Penalties are one of many measures aimed at managing the risk of non-compliance. Reviewing the costs and benefits of different penalties is an integral part of maintaining an up-to-date risk management strategy. The following are two instances where the Agency could benefit from a review of the current penalty structure:

- Civil penalties apply when a taxpayer is late in filing a tax return. But no civil penalties apply if a taxpayer refuses to file a tax return. The Agency's ultimate recourse is to prosecute the taxpayer, which is expensive.
- There are no automatic penalties based on audit adjustments that exceed a given amount, or a percentage of amounts, reported by a taxpayer.

5.75 The Agency's risk assessment systems highlight situations where a GST/HST registrant is claiming a refund but is in default regarding the obligation to file a tax return. In 2003, in the southern Ontario region alone, over 20,000 GST refund claims were referred to tax services offices for review because registrants might not be current in filing their tax returns. At present, the *Excise Tax Act* does not allow the Agency to refuse a GST/HST refund to individuals and corporations for not having filed their income tax returns.

5.76 **Recommendation.** The Canada Revenue Agency should

- complete a review of the penalty structure as discussed in its Future Directions Initiative and make appropriate recommendations to Finance Canada,
- consider seeking legislative authority to deny GST/HST refunds to registrants who are late in filing their tax returns, and
- obtain legislative authority for the changes made in July 2003 to penalties for late remittance of source deductions.

Agency's response: The Agency held extensive discussions with small and medium enterprises on the penalty structure. The predominant issue identified was the penalty of 10 percent on all late remittances of source deductions. The concern expressed was that this penalty did not properly recognize prior good performance and did not provide an incentive for paying the late remittance at the earliest possible date. Our current pilot project on the graduated penalties will allow the Agency to respond to this issue.

The Agency agrees that GST/HST refunds should be denied to registrants who are late in filing their income tax returns. It is reviewing both its GST/HST and income tax systems to ensure that there is an effective and efficient manner to identify these situations before GST/HST refunds are paid. It has also commenced discussions with Finance Canada on a legislative response.

The graduated penalties pilot project currently running is designed, among other things, to identify the implications of reductions in these penalties, which will assist in drafting legislative amendments. The Agency is working with Finance Canada to identify an appropriate legislative response to this issue.

Conclusion

5.77 The Agency is unable to provide us with an overall risk analysis to support its current resource allocation. Neither does it have sufficient information with which to make decisions on the required mix of compliance activities. As a result, it is difficult to determine whether its current resourcing decisions are most appropriate for each of its compliance activities, including its small and medium enterprise audit program.

5.78 The Agency uses computerized risk assessment systems, together with experienced auditors, to identify non-compliant taxpayers. Improvements to the current systems would increase their effectiveness.

5.79 The Agency's audit strategy for small and medium enterprises seeks to target taxpayers suspected of significant non-compliance. It also seeks to serve as a deterrent against non-compliance through its presence. However, tax services offices are staffed based on the population of different segments of taxpayers rather than on the risk or complexity that population presents. In addition, the current focus on audit coverage to meet targets agreed to with the Treasury Board Secretariat as a condition for funding reduces efforts to address cases of significant non-compliance. The Agency needs to evaluate the effectiveness of its strategy.

5.80 The Agency's own quality assurance reviews show weaknesses in the conduct of audits. The Agency needs to understand the reasons why auditors are not meeting the quality standards set for audits of small and medium enterprise taxpayers and needs to take corrective measures.

5.81 The Agency must gather additional information on audit results and analyze that information to better understand taxpayer behaviour, reasons for non-compliance, and methods of detecting non-compliance.

About the Audit

Objectives

The objectives of the audit were to assess how well the Agency

- understands the compliance behaviour of all taxpayers and allocates resources based on an integrated view of the risks to the tax base,
- allocates the resources available for audits of small and medium enterprises based on the risk of non-compliance,
- designs and implements audit activities to address non-compliance in small and medium enterprises, and
- measures the results of its activities.

Scope and approach

The audit covered the activities of the Compliance Research and Business Management Directorate concerned with small and medium enterprise compliance and the functional guidance provided by the Audit Directorate headquarters staff. It also included certain activities of the non-registrant and non-filer program within the Assessment and Collections Branch. The audit looked at the tax services office activities related to income tax and GST/HST audits of small and medium enterprises as well as activities aimed at getting individuals and corporations in the small and medium enterprise category to file their tax returns and register for the GST/HST.

We reviewed the Audit Directorate's plan for managing the risk of non-compliance in the small and medium enterprise population. We also reviewed the Compliance Research and Business Management Directorate's efforts at measuring the extent of non-compliance in the small and medium enterprise population and its systems designed to identify tax at risk for each taxpayer and GST/HST registrant. We examined documentation and conducted interviews at headquarters in Ottawa and in selected taxation services offices across the country.

We examined the Agency's quality assurance activities and reviewed quality assurance reports to gauge whether auditors complied with Agency standards in carrying out their audits.

The scope of our audit did not include other specialized Compliance Branch programs that cover all taxpayers, including small and medium enterprises. These programs include tax avoidance, international tax, scientific research, and other tax incentives. Nor did we look at the appeals program for reviewing contested audit decisions or at the tax collection activities undertaken for small and medium enterprises. Many of these programs have been subjects of past audits. Also excluded from the scope of this audit was the administration of GST in Quebec by the Ministère du Revenu du Québec.

Criteria

We would expect the Agency to

- undertake monitoring and research to identify compliance trends and problems, and estimate the extent of non-compliance for all taxpayers;
- translate this research into a set of compliance activities and allocate resources to ensure an effective check on non-compliance in the small and medium enterprise population;
- develop profiles of high-risk taxpayers;
- select and ensure that it adequately audits taxpayers of highest risk; and
- accurately record the results and evaluate the impact of these activities to improve future program planning and report on their effectiveness.

Audit team

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Report of the Auditor General of Canada to the House of Commons—March 2004

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2004

Report of the
Auditor General of Canada
to the House of Commons

MARCH

Chapter 6
Managing Government:
Using Financial Information

Office of the Auditor General of Canada

The March 2004 Report of the Auditor General of Canada comprises seven chapters, a Message from the Auditor General, and Main Points. The main table of contents is found at the end of this publication.

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Ce document est également disponible en français.

© Minister of Public Works and Government Services Canada 2004
Cat. No. FA1-2004/1-6E
ISBN 0-662-36246-2

Chapter

6

Managing Government

Using Financial Information

All of the audit work in this chapter was conducted in accordance with the standards for assurance engagements set by the Canadian Institute of Chartered Accountants. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.

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Managing Government

Using Financial Information

Main Points

6.1 The government continues to improve financial information, including successful implementation of full accrual accounting in its 2003 summary financial statements. Making this change to the current year's summary financial statements was a significant accomplishment. The government should be proud of the results of this hard work and of the fact that the enhancements have established Canada as a world leader among national governments in financial reporting.

6.2 However, the adoption of accrual accounting in the summary financial statements was never intended as an end in itself, but rather as part of a wider initiative to improve financial management and control in the government. More work is still needed to resolve a number of outstanding issues.

6.3 Departments and agencies must now improve and use accrual financial information for their daily decision making and management and reporting practices; otherwise accrual accounting will be seen as something that is undertaken only to comply with initiatives or directives established by central agencies, such as the Treasury Board Secretariat.

6.4 The Office of the Comptroller General of Canada needs to lead this change by leveraging the momentum created by recent successes and by aggressively advancing financial management and control within the government. It also needs to develop a strategy to strengthen the financial capacity of senior financial positions and ensure that a strong departmental comptrollership capacity is established in all departments.

6.5 The government must finalize its study of accrual-based appropriations and budgeting at the departmental level. The Treasury Board Secretariat continues to state that this complex issue needs extensive study before a decision can be made, even though the government has been examining the issue for several years.

6.6 Departments and agencies must take additional and speedier action to correct weaknesses in their internal controls. Integrated and comprehensive internal control systems play a significant role in ensuring that high-quality financial information is available. After three years of examining internal control systems within departments and agencies, we continue to observe weaknesses similar to those we first identified in 2001.

Background and other observations

6.7 Complete financial information and strong internal controls are vital for achieving results for Canadians. The integration of financial and non-financial information into decision making, the establishment of effective financial information systems and controls throughout government, and the establishment of strong financial policies and procedures all lead to continuous improvements of stewardship in government.

6.8 Accrual financial information is an integral component of good financial information in government. Under accrual accounting, transactions and other economic events are recognized when they occur, rather than when cash or its equivalent is received or paid. Expenses are recorded in the period when the goods or services are consumed, revenues are recorded in the periods to which they pertain, and the multi-year economic benefits associated with capital assets are recognized in the period in which they are used.

6.9 Accrual financial information helps users appreciate the full financial scope of government—the resources, obligations, financing, costs, and impacts of its activities, including the costs of consuming assets over time. This more complete picture enables legislators to hold the government more accountable for the stewardship of its assets, the full costs of its programs, and its ability to meet short-term and long-term financial obligations.

6.10 Accrual financial information can also help improve decision making within departments. Managers will improve their focus on the stewardship of assets and liabilities under their control, consider the full periodic costs of providing services, and examine how the full range of costs might affect their use of public funds and assets.

6.11 The current operating environment within government encourages managers to focus on the amount of their original allotment of money left to spend (free cash balance) and not on the full accrual cost of their programs and activities. As a result, full cost information is not considered as important as cash expenditure information. This orientation by managers arises because, among other things, the basis of accounting used in the government's expenditure management system is not accrual accounting, and it is this system and its allotments against which most departmental and agency managers still feel the greatest accountability.

6.12 As well, the government's current model for departmental financial statements needs further improvement because it does not require recording and disclosure of some significant costs and liabilities and the valuation adjustment of some assets. In our view, without this information, departmental financial statements do not provide accurate and reliable information on departments' program costs and assets and liabilities.

The Treasury Board Secretariat has responded. The Secretariat has agreed with our recommendations, and its responses in the chapter describe current or planned actions to address the recommendations.

Introduction

What is financial information, financial management, and internal control?

6.13 Providing information is an important role of the government. The Chief Information Officer Branch of the Treasury Board Secretariat acknowledges the importance of this role in the preamble to its *Framework for the Management of Information in the Government of Canada*. It states that "all of the services that we [government] provide to citizens, to businesses, and to internal clients are about information in one way or another. The provision of information is often the service itself . . . . Fundamentally, most government activities are about managing information."

6.14 Financial information is an integral part of the government's activities and reflects the information arising from its financial affairs and transactions. For example, as reported in the 2002–03 *Public Accounts of Canada*, the government raised over $190 billion in revenue, incurred expenses of over $183 billion, and had assets of almost $190 billion and liabilities of about $700 billion. Knowing where this money originates and how it is used is important to government decision makers, parliamentarians, and Canadians.

6.15 Financial management is a term that is used to reflect some of the important activities that financial and program managers in departments and agencies carry out when delivering programs and services and exercising stewardship over resources for which they are responsible. Some of these activities include the following:

- providing timely, relevant, and reliable information (both financial and non-financial) to support decision making and to support the management of risks in the organization;
- establishing control systems and procedures to manage and protect the integrity of that information;
- safeguarding resources, accounting for their use, and ensuring compliance with relevant authorities; and
- monitoring actual results by producing reports that compare actual information (both financial and non-financial) with budgeted or planned information, and taking corrective action when desired outcomes or results are not achieved.

6.16 Internal control refers to management's action to mitigate risks and achieve established objectives. Controls are needed to safeguard assets; reduce the risk that financial and non-financial data may be incorrect or corrupt; reduce the potential consequences of errors in financial and non-financial data; ensure proper authorization of transactions and compliance with policies, procedures, laws, and regulations; and ensure the economical and efficient use of resources.

Financial management is a core component of government management initiatives

6.17 In Chapter 7 of this Report, we discuss the Treasury Board Secretariat's role in the management of government. Elements of that discussion highlight the role of financial management in the Secretariat's legislative responsibilities, in past royal commissions on government operations, in *Results for Canadians: A Management Framework for the Government of Canada (March 2000)*, and in other recent initiatives.

6.18 Of particular importance has been the Comptrollership Modernization Initiative and its discussion of financial management and control. The government undertook this initiative to strengthen management capabilities in departments and agencies. Specifically, its objectives relative to financial management and control were to develop standards and practices for integrating financial and non-financial performance information into a meaningful whole, to communicate that information to those who need it, to properly assess and manage risk, and to ensure appropriate control systems.

6.19 In its recent interim report entitled *Modern Comptrollership Initiative: A Progress Report on Government-wide Implementation*, the government recognizes that departments and agencies have further work to do before the principles of modern comptrollership are incorporated into the public service culture and management practices.

6.20 Another key initiative in recent years was the Financial Information Strategy (FIS). The strategy was to facilitate the meaningful use of financial data, including accrual accounting information, and to more closely link costs with activities, operations, and results.

6.21 The Financial Information Strategy had three objectives:

- Departments and agencies would select one of seven systems approved by the Treasury Board Secretariat and implement new financial information systems that would support the full accrual method of recording and reporting financial transactions.
- The government would develop new accounting policies that comply with Canadian generally accepted accounting principles for the public sector. Departments and agencies would apply these policies and take primary responsibility for the quality and completeness of detailed information. They would also produce auditable annual financial statements.
- Government managers would have access to better financial information and use it in their day-to-day decision making.

6.22 Department and agencies have successfully installed information systems for supporting accrual accounting, and now the departments and agencies need to use the government's new accrual financial information in day-to-day decision making.

6.23 As part of the government's reorganization plan announced on 12 December 2003, the Treasury Board Secretariat has been streamlined to focus on comptrollership and financial management, including oversight of such matters in departments and agencies. Specifically, it will ensure that departments and agencies meet all requirements for expenditure planning, control, and oversight, and will consider policy proposals for the purposes of due diligence and value for money. There will also be a distinct Office of the Comptroller General in the Treasury Board Secretariat to enhance accountability, and the Comptroller General will be involved in selecting departmental comptrollers who will have a functional reporting relationship to the Comptroller General.

Why financial management and control is important to the government

6.24 A number of developments in both the public and private sectors have continued to draw attention to financial management and control practices of organizations. Examples include our recent report on the Office of the Privacy Commissioner, reported cases of inappropriate financial practices of public servants, and increased corporate governance expectations within the private sector. Canadians expect their government to respond to such problems and issues by improving its financial practices. This includes improving internal controls, the quality and use of financial information, and the capacity of government to address these issues.

6.25 The government has also invested considerable financial resources in improving financial information systems and introducing accrual financial information and principles of modern comptrollership. Government managers now have access to new and better forms of financial information, and they should be expected to use that information to better manage their programs and activities.

6.26 Managers can become more aware of the complete picture of their financial performance (all costs and revenues). Managers are then more inclined to consider all of those costs in making various decisions, such as the evaluation of the cost-effectiveness of in-house delivery versus contracting for services, the appropriateness of cost recovery policies, or the amount to charge other departments for services provided.

Focus of the chapter

6.27 The subject of financial management and control has been a long-standing focus of the Office of the Auditor General of Canada. The Office has carried out a number of audits that have monitored the government's progress toward achieving modern comptrollership, implementing the Financial Information Strategy, and managing financial information.

6.28 In this chapter, we continue the focus of our December 2002 Report, Chapter 5, Financial Management and Control in the Government of Canada, and further explore the government's progress in implementing accrual accounting, accrual appropriations and budgeting at the departmental level, and appropriate systems of internal control. We also examine the government's progress in providing the necessary leadership and support to change the way that financial information is used in government.

6.29 In our approach we relied on the nature, scope, and extent of our audit of the summary financial statements of the Government of Canada. As a result, we derived our observations and findings from that audit and also from other audit work done by our Office in assessing financial management and control in the government. Further details are included at the end of the chapter in **About the Chapter**.

Observations and Recommendations

6.30 The Office of the Auditor General of Canada continues to recognize the federal government's many achievements in financial management and control (Exhibit 6.1). It also congratulates the government on the successful implementation of accrual accounting in the summary financial statements.

Exhibit 6.1 Recent achievements in financial management and control

In our December 2002 Report, Chapter 5, Financial Management and Control in the Government of Canada, we recognized that the government had made progress in advancing financial management and control practices. Among the achievements noted were the following:

- The Treasury Board Secretariat developed a series of accrual accounting policies and departments implemented those policies.
- The Secretariat established a strategy for the next phase of the Comptrollership Modernization Initiative and issued guidance to departments and agencies on preparing implementation plans.
- Departments completed self-assessments on their capacity for modern comptrollership and prepared implementation plans in response to their findings.
- Departments and agencies successfully implemented one of the Secretariat's recommended information systems.

Since our December 2002 Report, the government has continued to make progress in guiding and advancing management control processes and practices. Among the more recent achievements are the following:

- The Treasury Board Secretariat developed its *Management Accountability Framework* to provide departments and agencies with guidance on implementing the principles of the government's overall management framework.
- The Clerk of the Privy Council Office's Deputy Minister performance agreements have continued to make modern comptrollership a priority.
- The Clerk and the Secretariat jointly developed and issued guidance to deputy heads that clarified their roles and responsibilities.

In the *Observations of the Auditor General on the Financial Statements of the Government of Canada for the Year Ended 31 March 2003*, improvements recognized included the following:

- implementation of accrual accounting for the 2002–03 *Public Accounts of Canada*, including the recognition of over $47 billion in tangible capital assets;
- early adoption of the new financial reporting model for senior governments recommended by the Public Sector Accounting Board of the Canadian Institute of Chartered Accountants;
- addition of budget information to the summary financial statements to enable the comparison of actual results with budgeted results; and
- inclusion of a section to the *Public Accounts of Canada* that provides an executive overview of the summary financial statements and the significant activities during the year that affected those statements.

6.31 Although the government has continued to make progress since our December 2002 Report, Chapter 5, the results of our most recent audit of the summary financial statements of the Government of Canada indicate that elements of financial management and control still need to be improved. This conclusion is consistent with the findings of the Treasury Board Secretariat's reviews, as acknowledged in its 2003 Performance Report.

Challenges ahead

Central and departmental leadership and support is still important

6.32 Our observations arising from the audit of the government's summary financial statements and from other recent audit work in the area of financial management and control have indicated that departments continue to experience key difficulties. These include not correcting weaknesses in their internal financial control systems on a timely basis, not making accrual accounting information an integral part of their daily decision making and financial reporting, and struggling with adjusting between full accrual financial information for general reporting purposes and cash-based financial information for appropriations and departmental-level budgeting. These issues are discussed in more detail later in this chapter.

6.33 Improving financial management and control in the government is not just a matter of recording transactions, preparing financial statements, or implementing internal financial control systems. These practices are merely the tools and processes that make improved financial management and control possible. The challenge for the government is to make these elements integral to the broader management framework of the government and incorporate them into the daily decision making and management practices of departments.

6.34 Accomplishing this challenge will require more than integrating these concepts in the modern comptrollership framework and the modern management accountability framework and more than simply providing guidance and sharing best practices on the implementation of each of these initiatives. Significant cultural changes and strong leadership from both the central agencies and senior departmental officials will be necessary to reinforce to departments and agencies that the government is committed to improving financial management and control—not just talking about it.

6.35 Departmental managers need to know why they should change. They will not likely change their behaviour or practices unless they perceive a benefit to doing so or a consequence to not changing. The reasons and objectives for change need to be clarified, and the tools and guidance for effecting change need to be provided to departments and agencies. This must all be balanced with effective monitoring and oversight.

6.36 Aspects of modern comptrollership continue to be included as a priority in the Clerk of the Privy Council Office's 2003–04 Deputy Minister performance agreements. This helps to keep financial management and control matters as a high priority. As well, deputy ministers and the Comptroller General of Canada continue to regularly discuss issues related to financial management and control, which helps to emphasize the importance of this priority to the government.

6.37 Regular monitoring and reporting of the key government initiatives that include elements of financial management and control, as well as developing related guidance, help to ensure that departments and agencies have the necessary knowledge and tools to address these initiatives. In the past year, the Treasury Board Secretariat has issued guidance and completed several reports that include elements of financial management and control. These include the following:

- interim reviews on the evaluation and internal audit functions of government;
- progress reports on the Comptrollership Modernization Initiative and the implementation of an integrated risk management framework; and
- a Management Accountability Framework that translates the vision of modern public service management, as established in *Results of Canada: A Management Framework for the Government of Canada (March 2000)*, into a set of management expectations and thereby provides deputy heads and all public service managers with a list of management expectations that reflect the different elements of current management responsibility.

6.38 In addition, the community of senior full-time financial officers has created a working group to explore opportunities to improve certain aspects of financial management and control.

6.39 Although these initiatives are significant, in its 2003 Performance Report, the Secretariat recognized that "in order to sustain progress, it is necessary to consolidate achievements and progress to date, deepen commitment to management excellence and broaden the agenda to build on modern comptrollership."

6.40 The reorganization announced on 12 December 2003 (see paragraph 6.23) also included commitments in the area of financial management. The government announced that it would strengthen leadership, oversight, and sound management of public resources. The Comptroller General is assigned overall leadership for improving financial management and accountability, including ensuring that departments and agencies comply with Treasury Board policies on strong expenditure control and rigorous stewardship of public funds. To help achieve this goal, the Comptroller General will review and sign-off on policy proposals to ensure that expenditure plans are sound and will be involved in staffing comptroller positions in departments and agencies. These positions will have a functional reporting relationship to the Comptroller General.

6.41 The continued leadership and support of senior management, both centrally and departmentally, is crucial to achieving the desired changes. Without it, the government's financial management and control initiatives risk losing momentum and becoming just another passing management fad. The February 2001 Report of the Auditor General of Canada, Reflections on a Decade of Serving Parliament, highlighted the danger that financial management and control could continue to be perceived as an isolated, unimportant function that senior managers can delegate to specialists and then give it little attention.

6.42 Our recent audit of the government's summary financial statements, our other audit work in the area of financial management and control, and Chapter 7 of this Report suggest that this danger still exists; more specifically, there is a danger of an implementation gap where good ideas fail to be translated into desired improvements in management.

6.43 As a result, the Comptroller General and senior departmental management need to take strong action to ensure that reform of financial management and control in the government takes hold. Exhibit 6.2 provides some suggestions for demonstrating commitment and leadership and advancing financial management and control issues within the government.

Exhibit 6.2 Examples of suggestions for demonstrating commitment and leadership and advancing financial management and control issues

- Obtain a clear commitment from senior management to the improvement of financial management and control and the use of financial information.
- Ensure that a financial management and control champion is appointed from the executive levels of management who has responsibility for establishing financial management and control.
- Ensure that the necessary resources are assigned.
- Monitor progress of financial management and control initiatives.
- Ensure that audit and management committees are engaged.
- Ensure that senior management is committed to and directly involved in financial management and control.
- Ensure that senior management sends clear messages about the importance of financial management and control to the achievement of strategic objectives.

Comptrollership capacity in departments needs building

6.44 In addition to leadership from the Comptroller General and the Treasury Board Secretariat, deputy ministers and senior departmental financial officials have a particularly critical role to play in improving financial management and control in government. This includes linking financial and non-financial information and ensuring that integrated performance information is used in decision making and in reviewing, assessing, and initiating appropriate systems of control.

6.45 Chapter 7 of this Report identifies the aforementioned issues among the key challenges facing the Treasury Board Secretariat in managing the government-wide implementation of the government's management agenda (including financial management and control initiatives). In particular, it notes that clear, visible, and active interest in and support for the management agenda among ministers, senior officials, and parliamentarians is critical for translating the agenda into concrete results.

6.46 Chapter 7 further notes that an important means of demonstrating support is to ensure that the Treasury Board Secretariat and departments have the people, resources, and tools to meet their management responsibilities. This conclusion is similar to that in our April 1997 Report, Chapter 3, Management of the Government's Accounting Function: A Central Agency Perspective. We stated that the government needed to assess the capability of accounting groups within departments and agencies to implement new systems and accrual accounting, and it needed to provide strong functional guidance to them, particularly during the period of transition.

6.47 As part of the reorganization plan announced on 12 December 2003, the government recognized the importance of departments and agencies having the right people with the right skills in financial management. In establishing the comptroller positions in departments and agencies, it will ensure that candidates receive thorough training to meet the requirements of the position and will target recruitment to ensure that well-qualified candidates are hired. As a result, it is clear that a critical success factor in improving financial management and control is to ensure that the management team accountable for financial management and control has the appropriate competency and skill. In most circumstances, this will mean that a large portion of this management team should have the necessary background and/or professional training in financial management and control.

6.48 In particular, we believe that some members of the management team would benefit from backgrounds and professional training in accounting. These qualifications would enable them to fully understand the impact of full accrual accounting on departmental decisions, such as the costing of activities and alternative delivery mechanisms, the assessment of the adequacy of revenues relative to costs in a cost recovery situation, and the analysis of capital asset acquisitions. These team members could also provide coaching and supervision to the staff charged with accurate and timely preparation of this departmental financial information and maintenance of adequate internal control.

6.49 We acknowledge, however, that incumbents of senior management positions in government have a broad range of experience and academic credentials and that management of an organization as large as the Government of Canada requires a balance of expertise and perspectives within the senior management ranks—not just a cadre of professional financial managers. Nevertheless, we continue to believe that a background and training in financial management, including accounting, is a beneficial attribute in championing financial management and control in departments, and we support the government in its latest decision to strengthen the comptrollership capacity within departments and agencies.

6.50 We also believe that internal audit staff and the departmental or agency audit committee can play an active role in providing the necessary support. As a result, both groups should be seen as an integral component in building the comptrollership capacity within departments and agencies.

6.51 **Recommendation.** The Comptroller General of Canada should develop a strategy and implement an action plan for promoting financial management and control initiatives and for improving the financial capacity in departments and agencies.

Treasury Board Secretariat's response. Various activities are already underway to promote financial management and improve capacity in departments and agencies.

The Treasury Board Secretariat developed the Management Accountability Framework (MAF) to provide deputy heads and all public service managers with management expectations, indicators, and measures that reflect the different elements of current management responsibilities and accountabilities, including financial management. The MAF is being used by departmental management and the Treasury Board Secretariat to assess and to identify areas for improvement in management practices.

Improved financial management is also being promoted through the requirement for both cash-based and accrual information in Treasury Board submissions and memoranda to Cabinet. The requirement forces development of the capacity to prepare, assess, and attest to accuracy of the information.

The recent establishment of the Comptroller General and Departmental Comptroller functions provides a unique opportunity to further strengthen management practices, controls, and accountability in the public service. The Comptroller General is committed to working with the senior financial community and to supporting all managers in achieving this goal. The addition of skilled departmental comptrollers in departmental management teams will improve the financial capacity in departments. Through the co-ordinated work of the financial, internal audit, and evaluation communities, departmental audit and evaluation committees, and the Auditor General's Office, the Comptroller General of Canada will put particular emphasis on improving departmental financial management and control.

Need to complete the study of accrual-based appropriations and budgeting

6.52 The Office of the Auditor General of Canada continues to be concerned about the pace of progress in addressing the implementation of accrual-based appropriations and budgeting at the departmental level. Also, as noted in our December 2001 Report, Chapter 1, Financial Information Strategy: Infrastructure Readiness, many departments suggested that unless the government moves to accrual-based appropriations and budgeting, managers will not focus on accrual-based information. Departments were virtually unanimous in asking that all financial information be produced on an accrual basis.

6.53 We recognize that a department's annual cash requirements will continue to be important information for Parliament. In our view, however, Parliament would be better served if it also received full program cost information based on accrual accounting as part of the estimates and appropriations process. This approach would ensure that Parliament received information comparable with the accrual-based information to be included in the *Public Accounts of Canada* and the government-wide budget. Furthermore, the information that managers and Parliament use in their decision making for appropriations would be on the same basis as these other aspects of government operations.

6.54 The Standing Committee on Public Accounts has continued to support our recommendations concerning accrual appropriations and budgeting (see Appendix) and has repeatedly urged the Treasury Board Secretariat to act on this issue.

6.55 In its April 2003 Report, the Standing Committee on Public Accounts repeated its recommendation from its December 2002 Report. Thus, it did not specify new target dates. The government's response continues to be that the issue is complex, of far-reaching impact, and without international consensus, and that it needs to be considered carefully. Meanwhile, the government continues to study the matter extensively and hold consultations with departments and agencies. It has recently developed a potential approach for further consideration and study, as well as a few interim measures for introducing accrual information in Treasury Board submissions for the management of capital resources. The reality, however, is that the government has not met any of the Committee's suggested target dates for resolving this issue.

6.56 Although this matter may indeed be a complex issue and may need to be considered carefully, other domestic and international jurisdictions have successfully addressed the issue of accrual-based budgeting and appropriations in the context of their own environments. After years of studying this issue and planning the 2003 government-wide Budget on an accrual basis, we would expect the government to have made more progress on the issue.

6.57 Until government-wide and departmental budgeting, financial reporting, and appropriations are put on a common basis, it is our opinion that effective use of financial management information in the government will not be achieved.

6.58 **Recommendation.** The Treasury Board Secretariat should promptly complete the study of accrual-based appropriations and budgeting at the departmental level and present the proposed approach for a common basis of planning, budgeting, and reporting, along with an implementation plan, to the House of Commons Standing Committee on Public Accounts.

Treasury Board Secretariat's response. The Treasury Board Secretariat recognizes that progress on accrual budgeting is slower than the Office of the Auditor General would like, but continues to believe that a prudent and thorough approach to examining and introducing accrual budgeting is appropriate. Progress has been made and continues to be made in examining and testing accrual budgeting options and monitoring accrual budgeting developments in other jurisdictions—both for those that have elected to introduce accrual budgeting and those that have not. As well, concrete steps have been taken to require accrual information for key parts of the government's decision-making process—specifically in memoranda to Cabinet and Treasury Board submissions dealing with incremental resources.

With completion of phase I of the accrual budgeting project, a specific work plan has been put in place for phase II, based on four key elements: interim arrangements (broadening the provision of accrual information in departmental transactions with the Treasury Board Secretariat beyond incremental resource submissions); Treasury Board Secretariat capital management policies (renew and update current Treasury Board Secretariat capital policy instruments in an accrual context); capital accrual budgeting pilots (testing the implementation of accrual capital budgeting in a range of departments); and ministerial/parliamentary consultations.

Need to improve and use accrual financial information for daily decision making

6.59 As described in the *Observations of the Auditor General on the Financial Statements of the Government of Canada for the Year Ended 31 March 2003*, fully adopting accrual accounting required the government's summary financial statements to include certain items, for the first time. These items include tangible capital assets, inventories, environmental liabilities, taxes receivable and payable, prepaid expenses, employee future benefits other than pensions, and a liability for estimated Aboriginal claims. As a result of these changes, tens of billions of dollars of assets and liabilities were recognized that had not been previously valued and recorded in the government's summary financial statements.

6.60 The observations also noted that the adoption of accrual accounting was never intended as an end in itself, but rather as part of a wider initiative to improve the government's financial management and control. For example, the recording of tens of billions of dollars of assets and liabilities should lead to better management of these items. The government's new accounting policies and its new financial information systems were only two elements of its Financial Information Strategy. They are essential building blocks supporting the third element of this strategy: providing government managers with access to better financial management information for their day-to-day decision making (see Accrual accounting—An initiative to improve decision making, page 14).

6.61 With the recognition of these additional accrual amounts and the implementation of the information systems supporting accrual accounting, departments and agencies now have the information and tools to enable them to provide accrual financial information. This will enable them to reflect a more complete picture of the full costs of their operations and program activities and stewardship of their assets and liabilities.

Accrual accounting—An initiative to improve decision making

Accrual accounting can help improve decision making within departments, for example, as follows:

- Managers increase their focus on the stewardship of assets because all assets are recorded in the financial accounts of the department. Managers become more aware of the assets under their control and the need to consider such issues as maintenance requirements, replacement policies, the identification and disposal of excess assets, risks such as loss caused by theft or damage, and the full impact of assets on service delivery.
- Managers increase their attention to the management of liabilities under their control because existing and potential liabilities are recognized. Managers become more aware of their responsibility for these liabilities and the need to develop plans for managing them, including identifying the impact of existing liabilities on future resources. If liabilities are not recognized, there is less reason for managers to consider certain issues and effectively manage those liabilities.

6.62 The challenge for the government is now to use this new accrual information effectively in its management decision making and ensure that this new basis of accounting is fully implemented in departments and agencies; otherwise the government will have invested a considerable amount of time and funds and will not have benefited from improved decision making in departments and agencies. Instead, full accrual information will be seen as something that is undertaken only to comply with initiatives or directives established by central agencies, such as the Treasury Board Secretariat.

6.63 Our recent audit of the government's summary financial statements, including observations reported in the 2002–03 *Public Accounts of Canada*, offers some examples of the need for departments and agencies to make accrual accounting an integral part of their management systems and practices and thereby improve their decision making. In each case, making this transition will require a greater degree of precision for the accrual financial information than is needed at the summary financial statement level.

National Defence needs to improve costing practices for its inventory

6.64 Of the $6.1 billion in government inventories, the largest amount belongs to National Defence and includes such items as ammunition and consumable supplies (for example, uniforms and machine tools). Historically, the Department had inventory systems that concentrated primarily on maintaining a record of quantities. The cost of that inventory was not emphasized because an ongoing valuation was not required. Inventory purchases were simply expensed when purchased.

6.65 With the full introduction of accrual accounting, the Department was required to validate the value of its inventory. During our recent audit of the government's summary financial statements, we found that the quality of National Defence's information systems and costing practices supporting its inventory systems did not easily provide accurate historical cost information related to inventory items. As a result, it was difficult for the Department to independently support the prices associated with its inventory.

6.66 Extensive additional work by National Defence as well as our audit work enabled us to conclude that the inventory figures were fairly presented, in all material respects, in the summary financial statements of the Government of Canada. National Defence, however, uses its inventory for more than simply financial reporting. It uses it to fulfil its departmental objectives of defending Canada and Canadian interests and values while contributing to international peace and security. As a result, National Defence requires information on the cost of its inventory for departmental decision making so that the Department can accurately forecast or report the costs of individual programs and activities. These activities are measured at a far less aggregated level than the summary financial statements of the Government of Canada.

6.67 The Department has begun to use accrual financial information in decision making (for example, analysis of the depreciation of capital assets) and has agreed to implement appropriate controls. These controls will ensure that the costs of future purchases in its inventory system relieve the costs of old inventory over time as the inventory is used. The controls will also enable the Department to properly monitor use and determine ongoing adjustments to reflect the obsolescence of inventory items. This improved approach to inventory costing will allow National Defence to better understand the value of its inventory at any time and provide the opportunity to consider an optimal value of inventory to be maintained.

6.68 Although National Defence has committed to making these improvements to its inventory practices, we remain concerned about the quality of its inventory costing. The Department faces a major challenge and it may be many years before its inventory records are suitable for improving management decision making.

Canada Customs and Revenue Agency tax receivables not consistently estimated

6.69 One of the most challenging and pervasive aspects of the government's changes related to accrual accounting was the accrual of tax revenue. As reflected in the summary financial statements, this change in accounting policy resulted in the recognition, for the first time, of tax receivables of about $43 billion, tax payables of about $33 billion, and an estimated allowance for doubtful accounts of $7 billion (the government's estimate of those receivables that will likely be ultimately uncollectible).

6.70 The Canada Customs and Revenue Agency is responsible for the management of these receivables and payables as part of its strategic goal of ensuring that Canadians comply with tax, trade, and border legislation. The allowance for doubtful accounts and the related annual provision for such losses is an important ingredient in assessing the cost of managing the government's portfolio of tax receivables. Pursuant to its agreements with the provinces and territories, the government absorbs 100 percent of the cost of any loss on collection of those receivables while being entitled to retain interest and penalties collected on those receivables.

6.71 Although the Canada Customs and Revenue Agency stated that it was reasonably confident in the process that it had followed in determining the accrual estimate for tax revenue, including its allowance for doubtful accounts, our audit of the government's summary financial statements identified problems with the estimate of the allowance for doubtful accounts.

6.72 Specifically, the Agency had its collection officers evaluate a sample of individual taxpayer accounts and estimate the amount, if any, of likely loss on collection. The Agency then used the summation of all of these estimates as its allowance for doubtful accounts. Our initial review of the Agency's estimate highlighted some inconsistencies in how Agency collection officers evaluated the collectibility of tax accounts. The Agency then undertook to redetermine the estimate of the allowance for doubtful accounts.

6.73 This additional work by the Agency and our extensive audit work enabled us to conclude that the tax accrual figures, including the allowance for doubtful accounts, were fairly presented, in all material respects, in the summary financial statements of the Government of Canada. The Agency uses this information in its financial reporting on the government's portfolio of tax receivables, and it represents the amount of tax loss that will likely be assumed by the federal government. This information is not only used for reporting in the government's summary financial statements but also in measuring the results of managing the government's portfolio of tax receivables.

6.74 The Agency has indicated that it will take additional corrective action to improve its assessment of the collectibility of tax accounts. The Agency and the Office of the Comptroller General should monitor these corrective actions to ensure that they result in improved information on which to base collection action and/or losses to be assumed by the government.

Departments and agencies need to consider impacts of financial information in other areas

6.75 The government's summary financial statements, like those of most other large organizations, include a number of significant management estimates. These estimates, an integral part of accrual accounting, affect billions of dollars of reported assets and liabilities. Examples of these estimates include the estimation of losses on loans and investments, the determination of the government's liability for pension obligations, and the estimation of losses arising from various claims against the government.

6.76 Departments and agencies are responsible for many of these estimates, and the determination of those estimates has a great impact on the financial position and costs of operations for those organizations. As a result, departments and agencies need to ensure that management processes include accurately developing, reviewing, challenging, and recording management estimates.

6.77 If attention is directed to ensuring that this and other financial information is prepared accurately and completely and on a timely basis, departments and agencies will know the full cost of delivering their programs and activities and therefore have better information for making daily management decisions (Exhibit 6.3 provides some examples).

Exhibit 6.3 Examples of the importance of full cost information for some federal organizations

- In addition to its role as the federal police force, the RCMP provides police services to most provinces and many municipalities on a contract basis. The RCMP needs high-quality information on the costs of the services it provides to its clients, to support the recovery of those costs in accordance with the contracts.
- The Department of Foreign Affairs and International Trade provides services overseas on behalf of other government departments and needs to know the cost of providing those administrative services so that other departments can pay their share of those costs.
- Transport Canada is required to capture and report full costs for its portion of the government's efforts to put new security measures in place.
- Alternative service delivery, outsourcing, and the creation of agencies highlight the need for information on total costs and on assets and liabilities managed by departments.

Source: April 2003 Report of the Auditor General, Chapter 2, Managing the Quality of Financial Information

6.78 Having information on the full cost of government programs and activities was also the fundamental issue in our December 2002 Report, Chapter 10, Costs of Implementing the Canadian Firearms Program. Recent discussions by parliamentarians during debates on possible amendments to benefits for veterans further illustrate the usefulness of having full cost financial information. Parliament considered not only the annual cash payments associated with the amendments to benefits for veterans but also the full estimated actuarial cost of providing these benefits over the life of the program. Thus, information was available on the possible impact on the annual surplus or deficit and the accumulated deficit—not just on the government's annual cash flow.

6.79 The Treasury Board Secretariat has established a number of departmental working groups and issued communications that are all designed to enable departments and agencies to share best practices, to understand the importance of accurate financial information, and to ultimately improve their management practices. As stated previously, however, the challenge for the government is to ensure that departments and agencies use this new accrual information effectively in their management decision making.

6.80 The Treasury Board Secretariat recognizes this challenge in its 2003 Performance Report. It states that the use of accrual accounting concepts in ongoing decision making and for improved accountability will need awareness and understanding by public service employees and parliamentarians. As a result, the successful implementation of accrual accounting in the decision-making processes of government will require collaborative action by the Treasury Board Secretariat and by departments and agencies.

6.81 **Recommendation.** The Comptroller General of Canada in conjunction with departmental and agency deputy ministers should ensure that departments and agencies have specific plans and strategies in place for improving and using accrual financial information at the departmental level and making that information an integral part of their management decision making. The Comptroller General of Canada should then monitor department's and agencies' progress in implementing those plans.

Treasury Board Secretariat's response. The Comptroller General of Canada agrees that accrual information provides better information for management and decision making and will continue to encourage departments to make full use of this information.

The requirement for both cash-based and accrual information in Treasury Board submissions and memoranda to Cabinet forces the consideration of accrual information in departments and agencies. The accrual information will, by necessity, become part of the process of preparing these documents and therefore be considered in decision making.

As noted in the chapter, further progress will be made on focussing managers' attention on accrual financial information and improving the use of that information with a move to accrual-based budgeting and appropriations.

Departments need to strengthen financial control systems

6.82 Since our December 2001 Report, Chapter 1, we have evaluated certain financial controls governing selected computer information systems, along with the related management and monitoring controls in 12 departments and agencies. In the past year, we continued our review of these controls in 6 departments and agencies. In total, these reviews have addressed the controls governing 25 of the key systems and applications of the largest departments and agencies. We intend to continue these reviews over the next few years so that eventually the 69 key systems and applications of the largest departments and agencies are reviewed (Exhibit 6.4).

6.83 Although there are many elements to internal control (paragraph 6.16), our objective for these reviews is to assess the quality of certain financial internal controls in selected financial information systems. We want to determine the extent to which the financial internal controls of various departments and agencies are sufficient to ensure the safeguarding of assets and that financial information is accurate, complete, and properly authorized.

6.84 After two years of reporting on the significant weaknesses in these controls, we have continued to identify the same weaknesses in our most recent reviews. As reported in our April 2003 Report, Chapter 2, Managing the Quality of Financial Information, departments have indicated a willingness to respond to these weaknesses. Departments and agencies

Exhibit 6.4 Scope of controls assessment work

	Entity
2001	Canadian Heritage (1)
	Agriculture and Agri-Food Canada (1)
	Canada Customs and Revenue Agency (2)
2002	Fisheries and Oceans Canada (1)
	Indian and Northern Affairs Canada (1)
	Department of Foreign Affairs and International Trade (1)
	Veterans Affairs Canada (2)
	Public Works and Government Services Canada (2)
	Canada Customs and Revenue Agency (3)
2003	Citizenship and Immigration Canada (1)
	Health Canada (1)
	Industry Canada (1)
	Correctional Service Canada (1)
	Transport Canada (1)
	Canada Customs and Revenue Agency (6)
2004 and beyond (planned)	National Defence (4)
	Royal Canadian Mounted Police (4)
	Canadian International Development Agency (1)
	Industry Canada (2)
	Health Canada (5)
	Fisheries and Oceans Canada (6)
	Transport Canada (3)
	Public Works and Government Services Canada (3)
	Agriculture and Agri-Food Canada (3)
	Human Resources Development Canada (4)
	Citizenship and Immigration Canada (4)
	Canada Customs and Revenue Agency (5)

Note: The numbers in parentheses represent the quantity of systems or applications covered by our assessments; they are matched with the departments and agencies responsible for those systems as at 11 December 2003.

involved in our first review (2001) have demonstrated varying degrees of improvement, with Agriculture and Agri-Food Canada showing significant improvement.

6.85 In many of the departments reviewed to date, we have noted that when controls exist, they are generally the detective type and not the preventive type that would exist if departments were using the automated capacities of the systems implemented. Preventive controls stop the wrong data from getting processed by the system and reduce the chance of the wrong information being included in the financial reports used for decision making.

Exhibit 6.5 Weaknesses in internal control systems that need particular attention

Systems	Weaknesses	Explanation	Implication
Electronic security controls	• User access rights and privileges reflect incompatible duties. • Super user accounts are not sufficiently controlled. • Users have wider system access than required. • Generic user IDs are used, which impairs accountability. • Best practices for key security parameters are not being enforced.	Electronic security controls are used to control user access rights and privileges within an electronic information system. Lapses in electronic security controls could allow for accidental or intentional corruption or loss of information. This can also result in the integrity of system tables and structures being compromised.	Inadequate electronic security controls could lead to unauthorized access, which can then lead to loss and/or corruption of data. This can result in erroneous reports being produced by the systems.
Monitoring controls	• Security administration function does not follow best practices. • Reconciliation of accounts is not being done on a timely basis. • Review of clearing and suspense accounts is not timely. • Policies and procedures for monitoring accounts are not always in place—for example, review of unusual or high-risk transactions and review of key performance measures such as "receivables aging".	Monitoring controls engage senior management in analyzing the reasonableness of financial information. Differences identified or matters observed must not only be highlighted but investigated and analyzed with corrective action taken. The security administration function is shared among many users and not controlled. There are no formal policies and best practices in place, leaving this position at risk.	A lack of monitoring controls allows errors to go unnoticed, thereby compromising data accuracy and validity as well as increasing the risk of loss and/or corruption of data.
New financial systems	• Integration of financial systems has not been achieved. • Many controls inherent in the new financial systems are not being used.	New financial systems have many capabilities but are often used to simply compile results produced from existing systems. In some cases, two or more systems are operating where integration may be possible. This approach to systems development and integration adds to the complexity and cost of maintaining financial information. There is also additional room for error if separate systems are maintained.	Not taking full advantage of the new systems capabilities results in lost opportunity to increase efficiency and effectiveness of the operations. Also, not using built-in controls could reduce the consistency of the controls.
Manual processing controls	• Segregation of duties is inadequate. • Documentation on policies and procedures is not being prepared/reviewed. • Quality assurance of the account verification process is limited.	Modern control frameworks should allow for proper integration of manual processing controls within an electronic framework. Manual controls are less systematic and less comprehensive in their application than electronic controls.	Bypassing the electronic framework increases the risk that data values will remain unchecked, be omitted, or result in duplicate information or other errors.
Selected authorities controls	• Payments are being certified without: - documentation of having received the goods; - proper delegation of signing authority; and - authorization.	Section 34 of the *Financial Administration Act* (FAA) requires that proper authorization be obtained and that goods or services have been received prior to any payment being made. Section 33 of the FAA requires that proper authorization be obtained prior to any requisition for a payment out of the Consolidated Revenue Fund and the subsequent charge against appropriations.	Without proper controls the government does not have assurance that payments are made only for goods or services that have been received.

6.86 With strong internal control systems being very important to risk management and to financial management and control, we have prioritized the control weaknesses arising from our controls assessments audit work that we believe should receive particular attention (Exhibit 6.5). While this is not an all-inclusive list of control requirements, we believe that these controls are the most critical to preventing and detecting errors. We also believe that these weaknesses, if present in a department or agency, need to be addressed within a reasonable period of time to avoid having an impact on decision making in departments.

6.87 We believe that the control weaknesses that we have identified are not insurmountable. With attention, most problems could be solved within a reasonable period of time.

6.88 As a result, we will start to formally assess and monitor the progress made by departments and agencies in addressing the control weaknesses we have noted. This progress will be reported in future chapters in the format outlined in Exhibit 6.6.

6.89 The Treasury Board Secretariat plans to issue high-level guidance on financial control frameworks that departments will be able to tailor to their specific needs. Currently, a broad strategy is being developed and some departments and agencies have expressed interest in participating in the development of the framework. In addition, the SAP financial systems cluster group (a user group that shares expertise in support of a financial system) has created a tool for generating user profiles to assist departments in managing user privileges.

6.90 While this guidance and direction should be helpful, the challenge for the government is similar to what it faces in implementing the use of accrual financial information by departments. The key is to ensure that departments continue to focus on the importance of the issue, on the different types of controls and control weaknesses, and on how to effectively implement the changes in their management processes so that the quality of their financial information is reinforced and improved.

Exhibit 6.6 Template for reporting progress of departments and agencies in responding to control challenges

	Electronic security controls	Monitoring controls	New financial systems	Manual processing controls	Payroll	Authorities
Department name						

● **Significantly addressed.** Most of the original significant audit finding has been fully addressed.

◕ **Satisfactory progress.** Substantial progress has been made in addressing the original audit finding, but some additional action is still required.

◒ **Some progress.** Some progress has been made in addressing the original audit finding, but considerable additional action is still required to achieve the desired results.

○ Unsatisfactory progress. Progress has not been made in addressing the original audit finding, and action remains outstanding.

6.91 As outlined in the revised Treasury Board Policy on Internal Audit, all internal audit functions in departments and agencies are repositioning their role to that of an assurance provider. In this role, they will likely be providing assurance on the completeness and accuracy of financial information for decision making and the related control systems and therefore can help to advance this issue within departments. As an example, in our controls assessment work with the Canada Customs and Revenue Agency, we have conducted our review of key controls jointly with the Agency's internal audit function.

6.92 **Recommendation.** The Comptroller General of Canada, in co-operation with departmental and agency management, internal audit groups, and audit committees, should ensure that departments and agencies identify and address the internal control weaknesses in financial accounting and information systems within a reasonable period of time.

Treasury Board Secretariat's response. The Comptroller General of Canada will follow up with senior financial management in departments on the control weaknesses found by the Office of the Auditor General.

The Comptroller General will also encourage departmental internal auditors and departmental audit committees to follow up on the Office of the Auditor General's findings and further improve accounting and systems controls.

Need to further improve departmental financial statements

6.93 As part of its accounting policy framework, the Treasury Board Secretariat requires departments to prepare auditable annual financial statements. Over the past two years, the Treasury Board Secretariat and departments and agencies have made significant progress in preparing departmental financial statements that contain some useful information about assets, liabilities, revenues, and expenses.

6.94 However, as noted in earlier observations on the Public Accounts of Canada, in our chapters on the Financial Information Strategy, and in our April 2003 Report, Chapter 2, the current model for departmental financial statements needs to be improved. It does not include some major costs, some liabilities, the valuation adjustments of some assets, certain liabilities maintained centrally by the Treasury Board Secretariat and services provided without charge by other government departments.

6.95 In our view, without this information, the departmental financial statements do not provide accurate and reliable information on a department's program costs and financial position. As a result, users of these financial statements are not getting a complete picture of the departments' costs of activities, assets, and liabilities, and are therefore making decisions without complete information. As well, without this information being reflected in the financial results of these departments, the departments responsible for the costs and liabilities are not being evaluated for their management of these items.

6.96 Preparing departmental financial statements so that they provide all of the necessary information and are ready for publication and audit would likely highlight for departments and agencies the importance of financial management and control concepts. As well, it would also provide an opportunity for departmental and agency internal audit to participate in the review of these financial statements and thereby contribute to their role as assurance provider. Also, departmental audit committees could become engaged in the oversight and approval of the financial statements.

6.97 The Treasury Board Secretariat has made some progress in improving the auditability of financial statements of certain departmental corporations and in devolving responsibility for certain balances managed centrally. The Secretariat has also indicated that the remaining departmental financial statements will not be published until they contain complete information. Since our December 2002 Report, Chapter 5, the Treasury Board Secretariat has been studying the remaining issues with input from departments and agencies to ensure that, in the future, departmental financial statements present information both fairly and fully.

6.98 **Recommendation.** The Comptroller General of Canada should promptly resolve the outstanding issues regarding departmental financial statements and establish a target date for finalizing the publication of departmental financial statements that would withstand the test of audit.

Treasury Board Secretariat's response. As noted in the chapter, departments and agencies have made significant progress in preparing financial statements. All departments and agencies are preparing accrual-based financial statements. The financial statements of many departmental corporations have been audited and included in the Public Accounts for many years. Starting in 2001–02, they were prepared on a full accrual basis of accounting.

With the adoption of full accrual accounting in the 2003 Budget and the government's 2002–03 summary financial statements, the Secretariat is now developing an approach for implementing the few remaining accrual accounting policies in departments and agencies. This involves the devolution of certain central accounting processes, such as allowances for losses on loans, contingent and certain other liabilities, and services provided without charge. As departments and agencies develop the capacity to record and report these amounts and we are satisfied that the financial statements are fairly presented, departments will be encouraged to publish them in departmental performance reports.

Conclusion

6.99 Financial information and strong internal control in the Government of Canada continue to be important components of good stewardship and effective management. They integrate financial and non-financial information into decision making and encourage the implementation of appropriate systems of control. The Office of the Auditor General of Canada continues to support the government's implementation of improved financial management practices, including the use of accrual financial information in daily decision making.

6.100 In the past year, the government has continued to make progress in advancing financial management and control in the government and has achieved a significant milestone in implementing improved financial reporting. After facing many challenges and with considerable effort, the government prepared its summary financial statements on a full accrual basis. These financial statements enhance the value of its financial reporting because it provides readers with a more complete picture of the government's financial position. As well, with the adoption of accrual accounting for its summary financial statements, Canada is now a world leader among national governments in financial reporting.

6.101 However, the adoption of accrual accounting in the summary financial statements was never intended as an end in itself, but rather as part of a wider initiative to improve financial management and control in the government. More work is still needed to resolve a number of outstanding issues.

6.102 Most importantly, as reported in our December 2002 Report, Chapter 5, Financial Management and Control in the Government of Canada, it remains essential that the government resolve the issue of accrual appropriations and budgeting at the departmental level. Although this issue is complex and needs to be considered carefully, the government has been studying it for many years and has made little progress. In our view, until government-wide and departmental budgeting, financial reporting, and appropriations are put on a common basis, effective use of financial management information in the government will not be achieved.

6.103 Departments must also strengthen their internal control systems, paying particular attention to electronic security controls, monitoring practices, the integration of manual and electronic processing controls, and the full exploitation of these systems.

About the Chapter

Objectives

For this chapter, we wanted to determine the extent of the government's progress in implementing accrual accounting and in implementing financial information systems designed to produce accrual-based financial information. We also wanted to determine whether the government had made progress in implementing accrual budgeting and appropriations.

Scope and approach

We did not develop a separate strategy and criteria for our work. Instead we relied on the nature, scope, and extent of our audit of the summary financial statements of the Government of Canada. As a result, we derived our observations and findings from the audit of the government's summary financial statements and from other audit work done by the Office of the Auditor General of Canada in the area of financial management and control in the government.

The procedures we followed included testing a sample of transactions and account balances, performing analyses, confirming year-end balances with third parties, reviewing significant internal controls as necessary, and discussing significant matters with government officials.

The audit of the summary financial statements was conducted according to Canadian generally accepted auditing standards. We assessed whether the summary financial statements were fairly presented in accordance with the government's stated accounting policies. Our resultant opinion and observations on matters related to accounting treatments and disclosures are included in the 2002–03 *Public Accounts of Canada*.

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Appendix Standing Committee on Public Accounts: Recommendations on accrual appropriations/budgeting and the government's response

Report date	Recommendation	Government response
December 1998	The Treasury Board Secretariat should complete its consultations with its stakeholders as quickly as possible in order to determine the best possible options to move the appropriations (supply) process to full accrual basis.	Progress is slower than anticipated. Response to a consultation paper is expected by 10 March 2000, from which recommendations to the government will be made in the following two or three months.
March 2000	The Treasury Board Secretariat should complete its consultations with departments and agencies on moving to accrual appropriations. Once the consultations are completed, the Treasury Board Secretariat should inform Parliament and the Public Accounts Committee in writing of its final decision and recommendations to the government on moving to accrual appropriations.	Responses to the consultation paper have been received and are being compiled and analyzed. Completion of the analysis is expected by September 2000, although further review of accrual-based budgeting and its relationship with appropriations may be required.
March 2001	The Treasury Board Secretariat should complete its consultations with parliamentarians aimed at determining the best possible options to convert the appropriations (supply) process to a full accrual basis and report the results to the House of Commons by 31 March 2002; the Government of Canada should move to an accrual-based system of appropriations (supply) by 1 April 2003.	The subject of accrual-based appropriations is very complex and requires careful review and consultation. Any decision made will have tremendous impact and consequences for government. This strongly underlies the need for very careful, rigorous, and exhaustive study before making any decisions in the area.
May 2001	The Treasury Board Secretariat should undertake and complete the required studies and consultations on full accrual-based appropriations, and it should prepare a set of proposals and alternatives to be presented to the House of Commons Standing Committee on Public Accounts, no later than 31 March 2002.	The subject of accrual-based appropriations is very complex and requires careful review and consultation. The decisions made respecting any contemplated changes to our budgeting and appropriations practices will have tremendous impact and consequences for government. This strongly underlies the need for very careful, rigorous, and exhaustive study before making any decisions in the area.
December 2002	The government should adopt the integration of full accrual-based budgeting and appropriations into the Canadian Expenditure Management System, and advise the Public Accounts Committee when the decision has been made. Once the decision is made to move toward full accrual-based budgeting and appropriations, the Treasury Board Secretariat should immediately prepare an action plan together with an implementation timeframe and table both these documents with the Public Accounts Committee.	Adopting the integration of full accrual-based budgeting and appropriations into the Expenditure Management System could have far reaching implications for government and for Parliament. Unlike accrual accounting, there is not international consensus on the adoption of accrual budgeting. Those countries that have implemented accrual budgeting have adopted specific accrual tools to suit their specific need and to help them implement much broader reforms. Moreover, some countries have indicated that their accrual budgeting frameworks are not yet proven and may be subject to change in the context of lessons learned. We intend to learn from their experience.

Source: Adapted from reports of the Standing Committee on Public Accounts

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Chapter 7
Managing Government:
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Office of the Auditor General of Canada

The March 2004 Report of the Auditor General of Canada comprises seven chapters, a Message from the Auditor General, and Main Points. The main table of contents is found at the end of this publication.

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Ce document est également disponible en français.

© Minister of Public Works and Government Services Canada 2004
Cat. No. FA1-2004/1-7E
ISBN 0-662-36248-9

Chapter

7

Managing Government

A Study of the Role of the Treasury Board and its Secretariat

All of the study work in this chapter was conducted in accordance with the policies of the Office of the Auditor General for studies. The policies draw on the standards and practices of various disciplines. The Office used various methodologies and techniques in the development and presentation of the studies' findings.

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Managing Government
A Study of the Role of the Treasury Board and its Secretariat

Overview

7.1 Following on the heels of the 1994–95 Program Review, the government has embarked on an ambitious agenda aimed at strengthening management across the federal public sector. The objective is to ensure that the key elements of good management are in place and that they are working well together.

7.2 Today's management agenda reflects a number of recurring themes in public administration, including how best to manage money, people, and information so as to

- preserve public trust;
- enhance economy, efficiency, and effectiveness; and
- ensure transparency and accountability.

7.3 The Treasury Board of Canada and the Treasury Board of Canada Secretariat play the lead role in developing and refining the government's management agenda and overseeing its implementation across departments and agencies. In performing that role, they face a number of significant challenges.

- **Setting the tone from the top**: maintaining interest in, and support for, the management agenda among ministers, senior officials, and parliamentarians.
- **Matching mandate and capacity of the Treasury Board and its Secretariat**: defining core responsibilities and having the right people in the right places with the right information to meet those responsibilities.
- **Strengthening department capacity**: ensuring that departments have the resources and tools to meet their management responsibilities.
- **Establishing and maintaining effective working relationships with departments**: recognizing that management responsibilities are shared between departments and agencies using communications, co-operation, co-ordination, and information-sharing to allow each to do its part.
- **Maintaining momentum**: paying attention to the full management cycle—strategic direction, planning, implementation, monitoring, and improving—over an extended period for each reform initiative.
- **Making best use of the tool kit**: determining and applying which of the various means available for influencing departments and their employees works best under what circumstances.

Background

7.4 This study provides Parliament with information on the key challenges that the Treasury Board and its Secretariat face in developing, refining, and implementing the federal government's management agenda. The study is a first step in the development of a longer-term audit plan for the Office of the Auditor General, covering key elements of the federal government's management agenda and the Treasury Board's role in them.

7.5 As the study neared completion, the prime minister announced a number of changes to the federal government's management practices. Those most relevant to this study are

- the Treasury Board and its Secretariat to focus on overseeing government expenditures, including the ongoing reallocation of spending from lower to higher priorities;
- a distinct Comptroller General's office in the Treasury Board Secretariat to help ensure that departments comply with the Board's expenditure and stewardship policies and to provide functional direction to department comptrollers;
- a new Cabinet committee on expenditure review to control spending and to align it with the evolving priorities of the government;
- a new agency for public service human resources management to improve human resources management in the public service and to implement the government's modernization initiative; and
- a transfer of responsibility for the Government On-Line initiative from the Treasury Board Secretariat to Public Works and Government Services Canada.

Introduction

The federal government is the country's largest single enterprise

7.6 The federal government is the largest single enterprise in the country, with more than $180 billion in annual spending. Many federal ministers, therefore, are responsible for a portfolio of organizations the size of a major corporation.

Did you know?

- The federal government employs some 300,000 people (including military and Crown corporation personnel)—more than 2.5 times the number of Canada's largest private sector employer.
- It is the biggest landlord and the largest owner of office property in Canada.
- It is also—by a wide margin—the largest single buyer of goods and services.

7.7 Departmental and other legislation set out ministers' duties, which are usually quite general in character. They normally cover a variety of functions, including policy development, program implementation, and departmental administration. Ministers are responsible to Parliament for the exercise of those duties.

7.8 Ministers rely upon their deputy heads—their most senior public servants—for advice and support in the exercise of their duties. Deputies are accountable to their ministers, and to the prime minister through the clerk of the Privy Council. They play a particularly important role in the management of department resources, acting in this area almost entirely in the place of their ministers. In doing so, they are accountable to the Treasury Board and the Public Service Commission of Canada for authorities that have been delegated to them.

The role of the Treasury Board and its Secretariat

7.9 The Treasury Board is a committee of Cabinet responsible for overall management of the federal government's financial, human resources, and administrative activities. Its powers derive from more than 20 pieces of legislation. The main statute is the *Financial Administration Act*, which establishes the Board and its responsibilities (Exhibit 7.1).

7.10 Historically, the Treasury Board has had four main roles:

- **It is the government's general manager**. The Treasury Board establishes policies and standards for management practices in departments and agencies. The practices cover a wide range of areas, including procurement, audit and evaluation, and service delivery. The Board oversees the government-wide implementation of these policies and standards.
- **It manages money**. The Treasury Board prepares the government's expenditure budget (the Estimates) and examines, approves, and monitors program spending in departments.
- **It manages people**. The Treasury Board establishes the terms and conditions of work for the core public service, including collective bargaining and human resource policy.
- **It manages information**. The Treasury Board sets the standards for information and communications technology and for privacy and access to information.

Core public service—The departments and agencies that work most closely with ministers and that comprise about one half of the public service—some 150,000 people.

Exhibit 7.1 The Treasury Board's responsibilities under the *Financial Administration Act*

Responsibilities of Treasury Board

7. (1) The Treasury Board may act for the Queen's Privy Council for Canada on all matters relating to

(*a*) general administrative policy in the public service of Canada;

(*b*) the organization of the public service of Canada or any portion thereof, and the determination and control of establishments therein;

(*c*) financial management, including estimates, expenditures, financial commitments, accounts, fees or charges for the provision of services or the use of facilities, rentals, licences, leases, revenues from the disposition of property, and procedures by which departments manage, record and account for revenues received or receivable from any source whatever;

(*d*) the review of annual and longer term expenditure plans and programs of departments, and the determination of priorities with respect thereto;

(*d*.1) the management and development by departments of lands, other than Canada Lands as defined in subsection 24(1) of the *Canada Lands Surveys Act*;

(*e*) personnel management in the public service of Canada, including the determination of the terms and conditions of employment of persons employed therein;

(*e*.1) the terms and conditions of employment of persons appointed by the Governor in Council that have not been established under this or any other Act of Parliament or order in council or by any other means; and

(*f*) such other matters as may be referred to it by the Governor in Council.

Source: *Financial Administration Act*

7.11 On 12 December 2003, the Prime Minister announced that the Treasury Board will focus its efforts on managing money—ensuring that value is received and overseeing the financial management functions in departments and agencies. A new Cabinet committee on expenditure review, chaired by the president of the Treasury Board, will examine all programs to ensure they are aligned with government priorities.

7.12 The Board's responsibilities for the general management of the government affect the activities of more than 20 federal departments and some 100 other organizations, including agencies, Crown corporations, and tribunals. These organizations differ in terms of mandate, organizational structure, and relationship to the minister. This adds to the complexity of managing the government as a whole.

7.13 In doing its work, the Board is supported by its administrative arm, the Treasury Board Secretariat. In 2003–04, the Secretariat planned to spend $192 million on its operations and to employ the annual full-time equivalent of 1,358 people.

Shared responsibility for managing government

7.14 The Treasury Board and its Secretariat are the key, but not the only, players responsible for managing the federal government:

- **Privy Council Office**. The clerk of the Privy Council is head of the public service and is responsible for its overall effectiveness and its competent and efficient management and administration. The Privy Council Office advises the prime minister on appointments of deputy ministers and heads of agencies and on the structure and functioning of government. The Privy Council Office also advises the prime minister, Cabinet, and policy committees of Cabinet on specific proposals in the Budget, focussing on overall government and prime ministerial priorities.
- **Department of Finance Canada**. The Department plans and prepares the federal government's budget, setting the level and composition of government revenues and spending. Departments and agencies conduct their activities within this resource framework.
- **Public Service Commission of Canada**. The Commission is mandated by Parliament to ensure a public service that is competent, non-partisan, representative of the Canadian population and able to serve the public in the official language of their choice.
- **Canadian Centre for Management Development**. The Centre supports the training and development of public servants.
- **Departments and agencies**. These provide advice on policy development and implementation to ministers, deliver programs and services, and ensure effective administration. They are responsible for following the policies and standards established by the Treasury Board, the Public Service Commission, and the new Public Service Human Resources Management Agency of Canada.

7.15 On 12 December 2003, the Prime Minister announced two additions to the government's overall management practices.

- A new **Cabinet committee on expenditure review**, chaired by the president of the Treasury Board. The committee will review all programs and expenditures to ensure that spending remains under control and is closely linked to the evolving priorities of the government. A secretariat, established within the Treasury Board Secretariat, will provide support to the Expenditure Review Committee.

- A new **Public Service Human Resource Management Agency of Canada**. The Agency will be established under the president of the Queen's Privy Council for Canada to strengthen human resources management and to implement the newly legislated human resource reforms.

Focus of the study

7.16 In previous reports, the Office of the Auditor General examined many aspects of management within the federal government. This study provides Parliament with information on the key challenges that the Treasury Board and its Secretariat face in developing, refining, and implementing the federal government's management agenda.

7.17 The study is a first step in the development of a longer-term audit plan for the Office and covers key elements of the federal government's management agenda and the Treasury Board's role in those elements. Over the coming years we will report on how the agenda has evolved and been implemented. Further details on the study are at the end of the chapter in **About the Study**.

Study Findings

Managing government: A brief history

7.18 Exhibit 7.2 presents key milestones in the management of the federal government. The day after Confederation, the Prime Minister established the Treasury Board as a committee of Cabinet to assist ministers in the overall financial control of the federal government. Chaired by the minister of Finance, its main role was to prepare the government's spending estimates for review by Parliament. In doing that, it needed to reconcile the competing demands for money from within the government.

7.19 In the years following Confederation, broad weaknesses in the federal government's administration became apparent. Ministers and their deputy ministers were unable to maintain adequate control over the use of people and money. The Treasury Board responded by issuing administrative procedures for departments to follow. And a permanent Civil Service Commission was established to make appointments to the public service.

7.20 Since then, there has been a series of studies of management in the federal government. While they have taken many different forms—royal commissions, parliamentary committees, academic analyses, external and internal task forces—the common question has been how best to achieve probity and prudence in the management of money, people, and information in order to

- preserve public trust;
- enhance economy, efficiency, and effectiveness; and
- ensure transparency and accountability.

Some useful concepts

Probity—The adherence to the highest principles and ideals.

Prudence—Skill and good judgment in the use of resources.

Economy—Getting the right amount of resources, of the right quality, delivered at the right time and place, at the lowest cost.

Efficiency—The minimum resources used to achieve a given quantity and quality of output.

Effectiveness—The extent to which the outcomes of an activity match the objective or the intended effects of that activity.

Transparency—Operating in a manner that is clear and easy to understand.

Accountability—The obligation to render an account, and accept responsibility for, one's actions, both in terms of the results obtained and the means used.

Exhibit 7.2 Managing government: a brief history

1867	Treasury Board established to assist ministers with financial control of federal government.
1878	First independent Auditor General of Canada appointed.
1918	*Civil Service Commission* set up to promote merit in staffing and classifying public service positions.
1931	Comptroller of the Treasury created to help Treasury Board provide assurance that money spent only as authorized by Parliament.
1938	Presentation of government spending estimates revised to provide more clarity on the cost of government activities, and responsibility for them.
1951	*Financial Administration Act* transfers authority to make final decisions on a broad range of financial and personnel matters from Cabinet to Treasury Board.
1961	*Civil Service Act* upholds independence of Civil Service Commission, its responsibility to protect merit principle, and its authority over recruitment and promotion.
1962	Royal Commission on Government Organization, headed by J. Grant Glassco, recommends that Civil Service Commission and Treasury Board "let managers manage" by removing some constraints imposed on departments.
1966	Treasury Board Secretariat separates from the Department of Finance, headed by own minister in order to focus on management of federal government.
1968	*Public Service Staff Relations Act* gives public service employees right to bargain collectively and strike. Treasury Board responsible for representing government in bargaining.
1969	Position of Comptroller General abolished; *Financial Administration Act* amended to place primary responsibility for accounting, budgetary and financial control with deputy heads of departments and agencies.
1976	Auditor General reports that Parliament and government are losing control of the public purse.
1977	Auditor General's mandate expands to include assessing how well government manages its affairs.
1978	Office of the Comptroller General established to report to Treasury Board on financial management, program evaluation, and internal audit in government departments.
1979	Royal Commission on Financial Management and Accountability, chaired by A. Lambert, recommends greater parliamentary scrutiny of government fiscal plan and Estimates. Commission also recommends stronger oversight by Treasury Board as a "board of management" with more capacity to scrutinize department plans.
1985	*Access to Information Act* and *Privacy Act* provides Canadians with rights to access government records and to protection of personal information against unauthorized use.
1989	Public Service 2000 set up to renew public service and improve service to the public.
1992	Clerk of the Privy Council named head of Public Service.
1993	Office of the Comptroller General amalgamates with Treasury Board Secretariat; position of Chief Informatics Officer established.
1994	Program Review–a comprehensive review of all government programs to determine best way of delivering them–begins.
1997	Prime Minister names Treasury Board as the government's management board.
2000	Government releases *Results for Canadians*; a framework for strengthening management practices across federal government.
2003	Treasury Board Secretariat releases *Management Accountability Framework*; a comprehensive model for improved management across public service. *Values and Ethics Code for the Public Service* also released. *Public Service Modernization Act* consolidates Treasury Board's responsibilities as employer. New agency for public service human resources management is created to manage implementation of Act; Treasury Board and Secretariat focus on financial oversight.

The federal government's general manager

7.21 **Treasury Board's role**. The Treasury Board is often referred to as the federal government's general manager. It establishes policies and standards for management practices in a wide range of areas (Exhibit 7.3), and oversees their implementation across the federal government.

Exhibit 7.3 The government's general manager: The role of the Treasury Board and the Secretariat

The Treasury Board provides the policy framework for the government's administrative practices and for its assets. The Secretariat supports the Treasury Board's role by

- establishing policies and standards to improve management practices in departments and agencies in the following areas
  - access to information
  - accounting
  - evaluation
  - financial management
  - human resources management
  - information and communications technology
  - internal audit
  - official languages
  - privacy
  - procurement and project management
  - real property and materiel management
  - security
  - service delivery
  - strategic systems and infrastructure
- overseeing the government-wide implementation of these Treasury Board policies and standards
- setting the standards for parliamentary reporting by government departments and agencies, both departmentally and for issues that cut across departments.

Source: Treasury Board of Canada Secretariat, *Report on Plans and Priorities, 2003–04*

7.22 The Treasury Board has always had an impact on overall management within the federal government, flowing from its responsibilities for managing money and people. However, the Great Depression provided the catalyst for a broader general manager role. Weaknesses in the federal government's financial systems became apparent, and the Treasury Board introduced administrative controls directed mainly at achieving economies in government.

7.23 By the end of the Second World War, central management had become an ongoing responsibility of the Treasury Board. But the many routine administrative matters directed to the Board required Cabinet approval. In 1951, to allow Cabinet to focus on the post-war social, economic, and international policy agenda, Parliament passed the *Financial Administration Act*, which allowed the Treasury Board to make final decisions on routine matters.

7.24 With these powers, the Treasury Board held authority over the management of the public service. It also became increasingly involved in scrutinizing the day-to-day details of department operations. While Cabinet focussed on broad questions of policy, the Treasury Board discussed the particulars of the policy and determined the scale of activities.

7.25 **Letting managers manage**. In 1960, amidst growing concerns about the quality of management in the public sector, the government established the Royal Commission on Government Organization chaired by J. Grant Glassco. The Commission examined the organization and methods of operation of the departments and agencies of the Government of Canada and recommended changes to promote efficiency, economy, and improved service.

7.26 The Commission's report, released in 1962, resulted in significant changes in the organization and management of the federal government. Exhibit 7.4 presents some of the key messages from the report. The report's theme: decentralization of authority in order to "let the managers manage."

Exhibit 7.4 Royal Commission on Government Organization (Glassco Commission): What was said

". . . in general, the defects in government are the consequence of outmoded concepts of public administration and do not reflect on the calibre of Canada's public servants."

"All told, the structure of control built up between 1918 and 1951 was impressive—and unique. Measured against the most narrow objectives, it was also unquestionably effective: the standards of probity reached by the Government of Canada in its use of people and money are high. But good management consists in more than the avoidance of sin, and this Calvinistic approach to public administration, while well designed to discomfit bad managers, was bound to prove most frustrating to good ones."

"Your Commissioners believe that departmental management must be entrusted with the power of decision in many of the areas now being controlled by the staff of the Treasury Board. Leaving such detailed matters to the departments should develop a greater sense of responsibility among departmental managers. . . Treasury Board, freed of this detail, should concentrate on the essential task of reviewing the programmes and objectives of departmental management in relation to overall government policy."

Source: Royal Commission on Government Organization, 1962

7.27 **The government's management board**. The most significant institutional change flowing from the report occurred in 1966 with the creation of the Treasury Board Secretariat as a separate department. The Secretariat reported to its own minister—the president of the Treasury Board—and continued to support the Treasury Board as a committee of ministers. When announcing the change, the Prime Minister emphasized the government's desire to have the Treasury Board serve as the management board for Cabinet.

7.28 External scrutiny of management in government also increased. New legislation, the 1977 *Auditor General Act*, clarified and expanded the auditor general's responsibilities. The Act gave the Auditor General, who was already looking at the accuracy of financial statements, a broader mandate to examine how well the government managed its affairs.

7.29 The 1979 report of the Royal Commission on Financial Management and Accountability, chaired by Allen Lambert, picked up the management board theme. It recommended that the Treasury Board become a board of management to provide a single focus for the central management of the federal government. Its intention: that the board of management would be able to assure Parliament and the public that sound management practices were in place and operating in government (Exhibit 7.5).

Exhibit 7.5 The Royal Commission on Financial Management and Accountability (Lambert Commission): What was said

"After two years of careful study and consideration, we have reached the deeply held conviction that the serious malaise pervading the management of government stems fundamentally from a grave weakening, and in some cases an almost total breakdown, in the chain of accountability, first within government, and second in the accountability of government to Parliament and ultimately to the Canadian people."

"The philosophy underlying our entire approach is not just that managers of government should have the opportunity to manage the affairs that fall within their responsibility, but that they should also be required to manage them in a way that will best serve the public interest. While the Glassco Commission insisted that managers be free to manage, it is evident to us that they have not been able to use this freedom effectively."

"As for the Treasury Board and its Secretariat, we contend that they should play a fundamental role in the management of government and that the nature of this role should be reflected in a change of name."

"The Board of Management would provide a single focus for the central management of government, consolidating the responsibilities for personnel and financial management . . . . The activities of the Board of Management . . . should be directed toward monitoring departments and agencies in the administration of their programs and activities, ensuring the development and application of government-wide policies, practices, and standards for consistency and fairness in the management of people and money, and acting as employer for the purpose of collective bargaining."

Source: Royal Commission on Financial Management and Accountability, 1979

7.30 The Lambert Commission went beyond the 1962 Glassco Commission's suggestion to "let the managers manage." It argued that "the managers of government . . . should be required to manage in a way that will best serve the public interest." To do this, it advised strengthening accountability within government and from the government to Parliament. Only a small percentage of the Commission's recommendations, however, were implemented.

7.31 A 1983 report by the Auditor General also stressed the importance of striking a balance between management control and flexibility.

> We are not advocating a return to an unlimited "let the managers manage" philosophy or an indiscriminate reduction of regulations and controls. In the absence of incentives that exist in the private sector, central controls will continue to be necessary in the public service to achieve a satisfactory level of prudence, probity, and equity. The challenge is to achieve a balance between the requirement for central control and the need for an adequate level of managerial authority so that managers can be responsible and accountable.

7.32 Facing weakening economic conditions in the 1980s, governments in many member countries of the Organization for Economic Cooperation and Development began to examine their role and policies more closely.

The consensus: a need to modernize public service management to make the public sector more effective and affordable. The common themes were

- increasing focus on results and accountability;
- increasing delegation of authority from central agencies to departments and, within departments, to the lowest levels reasonable;
- streamlining and simplifying administrative systems; and
- creating a more businesslike approach to the management of resources.

7.33 These themes were evident in Canada's efforts to strengthen public administration. For example, in 1986, in response to criticisms that across-the-board administrative policies needed to be more sensitive to individual departments, the Treasury Board introduced the Increased Ministerial Authority and Accountability (IMAA) initiative. The Board reviewed its policies and procedures to provide ministers and senior officials with increased authority and flexibility and to enhance their accountability for achieving results in program delivery. However, by 1989, only 6 of about 30 departments had signed IMAA agreements with the Treasury Board.

7.34 In December 1989, the government introduced Public Service 2000, a process to reform and renew the public service by making it less rule-bound and more innovative, focussed on achieving results and serving the public. Public Service 2000 led to the Treasury Board delegating more authority to department officials. But it produced only limited results compared with the high expectations that public servants had for the process.

7.35 In 1997, following on the heels of the 1994–95 Program Review, the Prime Minister formally designated the Treasury Board as the Government of Canada's management board. Its focus: to help departments and agencies improve their management practices. *Results for Canadians*—released three years later—provided a framework and agenda to guide public service managers. It committed the Government of Canada to excellence in four areas:

- focussing on citizens in its design, delivery, evaluation, and reporting on activities;
- managing under the highest professional and ethical values;
- achieving results and reporting them in simple and understandable ways; and
- spending responsibly.

7.36 In 2003, the federal government issued two additional documents on overall management in the public service:

- The Treasury Board of Canada Secretariat's *Management Accountability Framework* summarizes the Secretariat's expectations for modern public service management (Exhibit 7.6). The Secretariat will use it as the basis for discussion with deputy ministers and heads of agencies on management practices in their organizations and on priorities for improvement. It will also serve as input from the Secretariat into the

Privy Council Office's assessment of those senior officials, and for the expenditure and management reviews that the Secretariat conducts.

- The *Values and Ethics Code for the Public Service* guides and supports public servants in all their professional activities. The Code forms part of the conditions of employment in the public service, and covers democratic, professional, ethical, and people values.

Did you know?

- In 2002–03, the federal government (including its consolidated Crown corporations) spent $183 billion.
- It had a net debt—total liabilities less financial assets—of $565 billion.
- It had almost $190 billion in assets, of which $47 billion were in capital assets—such as land, buildings, ships, and aircraft.

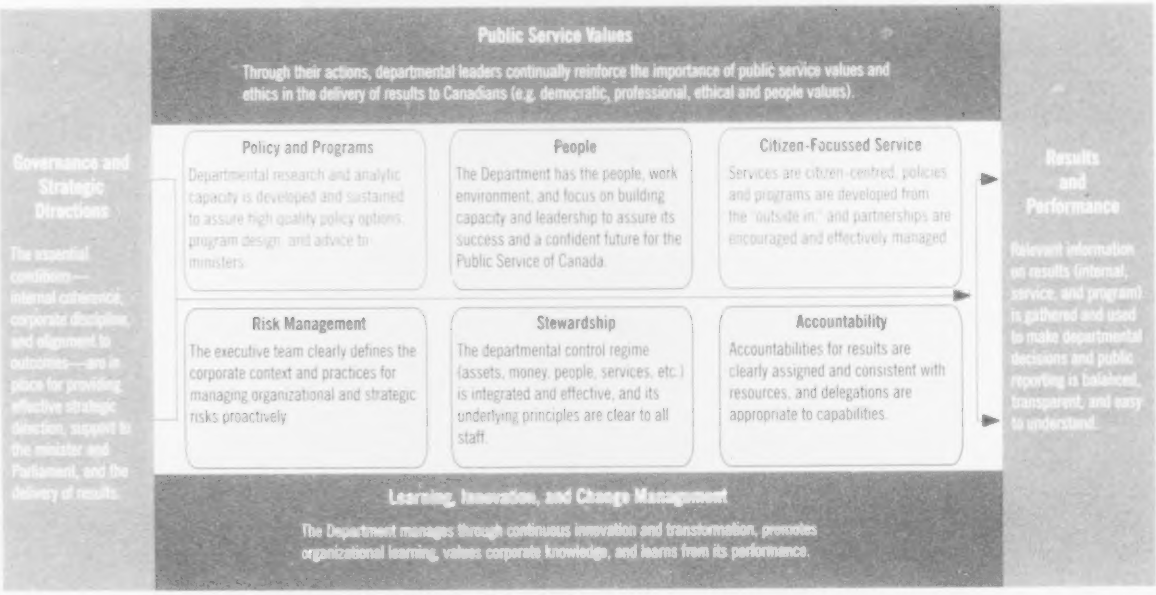
Managing money

7.37 **Treasury Board's role.** The Treasury Board's original role was to assist ministers in the overall financial control of the federal government, and this remains one of its key roles today (Exhibit 7.7).

7.38 Historically, the Finance department and its minister managed government spending. The minister of Finance chaired the original Treasury Board. The deputy minister of Finance also served as auditor general (a position held until 1878 when the first independent auditor general was appointed) and as secretary to the Treasury Board (a position held until 1947).

7.39 During its first 50 years, the Treasury Board had a small staff of Finance officials and dealt mainly with the form and nature of accounts, the transactions criticized by the auditor general, and the details of human resources administration. As responsibility for detailed human resources work shifted to the Civil Service Commission—the predecessor of today's Public Service Commission—the Board became more focussed on the Estimates.

Exhibit 7.6 Management Accountability Framework: The Secretariat's expectations



Public Service Values

Through their actions, departmental leaders continually reinforce the importance of public service values and ethics in the delivery of results to Canadians (e.g. democratic, professional, ethical and people values).

Governance and Strategic Directions

The essential conditions—internal coherence, corporate discipline, and alignment to outcomes—are in place for providing effective strategic direction, support to the minister and Parliament, and the delivery of results.

Policy and Programs

Departmental research and analytic capacity is developed and sustained to assure high quality policy options, program design, and advice to ministers.

People

The Department has the people, work environment, and focus on building capacity and leadership to assure its success and a confident future for the Public Service of Canada.

Citizen-Focussed Service

Services are citizen-centred, policies and programs are developed from the "outside in," and partnerships are encouraged and effectively managed.

Risk Management

The executive team clearly defines the corporate context and practices for managing organizational and strategic risks proactively.

Stewardship

The departmental control regime (assets, money, people, services, etc.) is integrated and effective, and its underlying principles are clear to all staff.

Accountability

Accountabilities for results are clearly assigned and consistent with resources, and delegations are appropriate to capabilities.

Results and Performance

Relevant information on results (internal, service, and program) is gathered and used to make departmental decisions and public reporting is balanced, transparent, and easy to understand.

Learning, Innovation, and Change Management

The Department manages through continuous innovation and transformation, promotes organizational learning, values corporate knowledge, and learns from its performance.

Source: Treasury Board Secretariat, *Management Accountability Framework*

Privy Council Office's assessment of those senior officials, and for the expenditure and management reviews that the Secretariat conducts.

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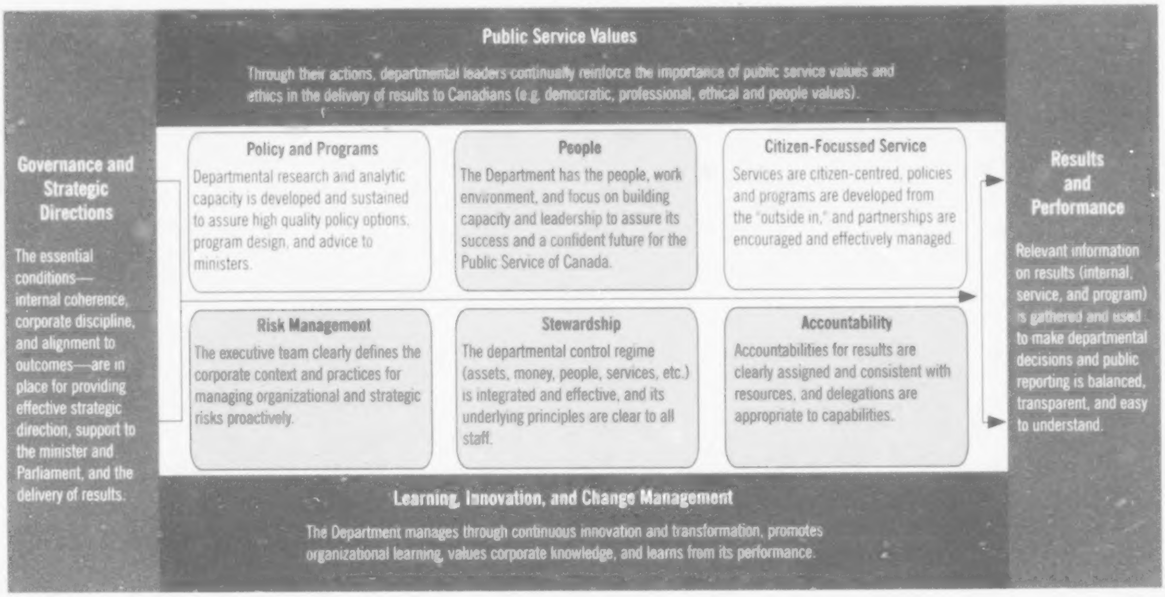

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Relevant information on results (internal, service, and program) is gathered and used to make departmental decisions and public reporting is balanced, transparent, and easy to understand.

Learning, Innovation, and Change Management

The Department manages through continuous innovation and transformation, promotes organizational learning, values corporate knowledge, and learns from its performance.

Source: Treasury Board Secretariat, *Management Accountability Framework*

7.40 **Treasury Board as comptroller.** The Treasury Board became a more important and active part of the federal government during the Great Depression. The government's efforts to respond to the financial consequences of the Depression were hampered by weaknesses in its financial management system. For example, it was difficult to determine amounts spent and contractual commitments made during the year until after the year was over. Departments also routinely overspent their budgets.

7.41 Faced with a severe financial challenge, the prime minister also assumed the position of minister of Finance, and chaired the Treasury Board from 1930 to 1932. Under his leadership, the Board began to play a stronger role as the government's comptroller, with a focus on economy. It issued several letters of refusal to department requests for new money and staff, reduced discretionary costs, and introduced controls on staffing and promotions.

7.42 The position of comptroller of the treasury, created within the Finance department, also helped the Treasury Board manage the budget system and reporting to Parliament. At that time, the comptroller employed a staff of 1,000 treasury officers and clerks posted in all departments, a number that grew to 4,700 by the early 1960s.

7.43 The comptroller maintained the accounts of the government and issued funds appropriated by Parliament. This latter pre-audit function—formerly the responsibility of the auditor general—ensured that all expenditures were authorized by Parliament.

7.44 The first major revision to the government's spending estimates took effect in 1938. Until then, department expenditures were listed under general headings, such as Civil Government or Miscellaneous. The cost of any one

Exhibit 7.7 Managing money: The role of the Treasury Board and the Secretariat

The Treasury Board is responsible for preparing the government's expenditure budget (the Estimates) and monitoring program spending in departments. The Secretariat supports the Treasury Board's role by

- establishing policies and standards to improve financial management practices in departments and agencies, and managing the government-wide implementation of them;
- allocating and re-allocating resources (focussing on non-statutory items such as the operating and capital budgets of government departments and agencies, payments to Crown corporations, and a range of transfer payments to organizations, individuals, and corporations);
- monitoring and analysis of the management of resources on a program, departmental, and sectoral basis;
- ensuring that resource management is integrated with the government's decision-making and priority-setting processes; and
- reporting on government expenditures.

Source: Treasury Board of Canada Secretariat, *Report on Plans and Priorities, 2003–04* department's activities could be included under several different headings. As a result, parliamentarians found it difficult to identify the cost of individual activities and who was responsible for them. In response, the Finance department regrouped the expenditures by department. It also grouped planned expenditures for each department according to the services and operations for which the department was responsible.

7.45 **A stronger Treasury Board**. During the 1950s, the scope of federal government activities expanded, bringing with it significant increases in government spending and personnel. Given its broad responsibilities, the Treasury Board became an increasingly important force in the government. With Cabinet focussed on policy issues, the Treasury Board concentrated on working out the details of policy implementation and resourcing. To do that, Treasury Board analysts needed a good understanding of the day-to-day operations of departments.

7.46 As noted earlier, the most significant institutional change flowing from the Glassco Commission report occurred in 1966, when the Treasury Board Secretariat separated from the Department of Finance. Responsibility for advice on economic, fiscal, and tax policy remained with Finance. The Secretariat assumed responsibility for the expenditure side of the budget.

7.47 **Departmental control over spending**. Changes in responsibilities continued through the late 1960s. In 1969, as recommended by the Glassco Commission, the position of comptroller of the treasury was abolished, and departments took responsibility for certifying and authorizing expenditures. The comptroller's office became part of the Department of Supply and Services.

7.48 At the same time, the government introduced the planning-programming-budgeting system. Emphasis shifted from allocating funds to the individual line items of department budgets to allocating funds on the basis of programs and their impacts.

7.49 **Loss of control**. By 1976, however, the Auditor General concluded that financial management and control in the federal government was inadequate and would likely remain so unless the government took strong action. Based on the study of financial management systems in departments, agencies, and Crown corporations, the Auditor General reported that "Parliament—and indeed the Government—has lost, or is close to losing, effective control of the public purse."

7.50 In 1978, as part of the government's response to the Auditor General's Report, a new office of the comptroller general was established. While similar in name to the former comptroller of the treasury, the function was different. The comptroller general reported to the Treasury Board on financial management, program evaluation, and internal audit in government departments. The office amalgamated with the Treasury Board Secretariat in 1993.

7.51 The Auditor General's Report also set the stage for the establishment of the Royal Commission on Financial Management and Accountability (the

Lambert Commission). The Commission's 1979 report recommended strengthening parliamentary control over government expenditures through greater scrutiny of the government's fiscal plan and the Estimates.

7.52 The federal government's Comptrollership Modernization Initiative began in 1997, with the creation of an Independent Review Panel. The Panel's report noted that modern comptrollership requires managers and financial specialists to work in a co-ordinated way to prioritize, plan, and meet operational goals and to achieve desired results. The Panel identified four key elements of modern comptrollership:

- integrated performance information (financial and non-financial, historical, and prospective);
- a sound approach to risk management;
- appropriate control systems; and
- a shared set of ethical practices and organizational values, beyond legal compliance.

7.53 In 1979, the government introduced a new policy and expenditure management system to better link spending to government priorities. Two new ministries of state focussed exclusively on policy co-ordination and spending. When they disbanded in 1984, Finance and the Privy Council Office became more involved in spending decisions.

7.54 In 1981, the Estimates documents were revised to provide information on program performance and accomplishments. The Estimates documents were presented in three parts: Part I set out the overall government expenditure plan; Part II contained the amounts requested for each department; and Part III included detailed information on activities and expenditures planned by individual departments.

7.55 **Restraining expenditure**. Expenditure management in the federal government during much of the 1980s and into the early 1990s involved a series of relatively small, across-the-board spending cuts coupled with occasional freezes on spending. At the same time, departments had access to policy and operational reserve funds, albeit in diminishing amounts.

7.56 By the late 1980s, however, it was apparent that the weakening fiscal situation, brought on by rising interest rates, could not be dealt with in that way. In 1989, the government established a new committee of Cabinet—the Expenditure Review Committee—to help ensure that spending was directed to the highest priorities and that spending restraint contributed to deficit reduction. The Committee was supported by officials from the Department of Finance and the Treasury Board Secretariat and identified spending cuts that were included in the 1989 Budget.

7.57 In 1994, the government launched a comprehensive review of all government programs to determine the most efficient and effective way of delivering them. Program Review, as it was called, was designed to significantly reduce spending. The Department of Finance established the total reduction needed to achieve the government's targets, and allocated that reduction to individual departments. Departments then found those savings, guided by six tests: public interest, role of government, federalism, partnership, efficiency and effectiveness, and affordability.

7.58 Beginning in 1996, through the Improved Reporting to Parliament Project, departments and agencies published their detailed spending plans in two new documents:

- a report on plans and priorities, tabled in the spring, and intended to establish performance expectations and outline the general direction the minister wanted the department to take during the next three fiscal years; and
- a performance report tabled in the fall for the previous fiscal year and intended to provide information on results achieved.

7.59 The 2003 Budget presented the commitment to make reallocation from lower to higher priorities an integral part of the way the government manages. The government also announced that the Treasury Board would lead an ongoing examination of all non-statutory government programs, drawing on the experience of the 1994–95 Program Review.

7.60 **A renewed focus on managing money**. On 12 December 2003, the Prime Minister announced several measures to strengthen financial management within the federal government:

- a focus by the Treasury Board and the Secretariat on the overseeing of government expenditures, including the ongoing reallocation of spending from lower to higher priorities;
- a distinct office of the comptroller general in the Secretariat to help ensure that departments comply with the Treasury Board's spending and stewardship policies and to provide direction to department comptrollers; and
- a new expenditure review committee of Cabinet to control spending and to align it with the evolving priorities of government.

Managing people

7.61 Good government depends on the performance of public servants. How they are recruited, trained, managed, and treated is of great importance to an effective public service.

7.62 **Treasury Board's role**. There are different legislative frameworks that govern human resources management for various parts of the public service. Historically, the Treasury Board has had an important role in managing people in the core public service—the departments and agencies that work most closely with ministers. However, the *Civil Service Act* of 1918 made the Civil Service Commission responsible for numerous human resources management responsibilities, including recruitment and promotion. At first the Board made appointments and oversaw compensation on behalf of ministers. Today, the Treasury Board is responsible for the overall terms and conditions of employment for the core public service (Exhibit 7.8).

Exhibit 7.8 Managing people: The historical role of the Treasury Board and the Secretariat

The Treasury Board establishes the terms and conditions under which the core public service attracts and retains the staff it needs to do its work. The Secretariat has supported the Treasury Board's role by

- establishing overall policies in areas within which department managers administer their organizations, such as learning, workplace well-being, employment equity, language of work, and public service renewal, and managing the government-wide implementation of them;
- negotiating with public service bargaining agents the terms and conditions of work for unionized employees as well as determining the compensation of excluded and unrepresented employees;
- managing the various pension and benefit plans provided for public service employees;
- supporting department managers by advising on human resources management issues and assisting in the renewal of the human resource community; and
- supporting the development, learning, and management of the leadership community up to and including the level of assistant deputy ministers.

On 12 December 2003 many of the Treasury Board Secretariat's responsibilities were transferred to the new Public Service Human Resource Management Agency of Canada.

Source: Treasury Board of Canada Secretariat, *Report on Plans and Priorities, 2003–04*

7.63 Following Confederation, parliamentarians and others debated the extent to which government appointments should be based on merit (fitness for the job) as opposed to patronage (support for a political party). A series of commissions recommended that appointments be based on merit, with staffing done using competitive examinations.

7.64 The 1882 *Civil Service Act* established a Board of three Civil Service Examiners to supervise examinations for appointment and promotion. The 1908 *Civil Service Amendment Act* established a permanent Civil Service Commission of two members to report on the operation of the *Civil Service Act* and to make all appointments. In 1918, the *Civil Service Act* established a Civil Service Commission of three members charged with recruitment, promotion, transfers, organization, classification, and compensation. The Treasury Board focussed on the cost of the public service.

7.65 In 1958, the report *Personnel Administration in the Public Service* (Heeney Report) recommended that the Civil Service Commission continue its independent and exclusive role in those functions relating directly to the maintenance of the merit system. It also recommended the Commission continue to retain final responsibility for recruitment, selection, appointment, and promotion. In 1961, a new *Civil Service Act* was created. This act preserved the independence of the Commission and the fundamental principles of the merit system, and gave public servants the right of appeal against promotions, transfers, demotions, suspensions, and dismissals.

7.66 **A stronger role for the Treasury Board.** In 1932, as part of its efforts to tighten control of spending during the Great Depression, the government established staff control regulations, reducing significantly the Civil Service Commission's responsibility for human resources management.

7.67 Following the Second World War, reports on the public service repeatedly asked what division of functions among the Civil Service Commission, the Treasury Board, and government departments best served the public interest. In 1951, the government concluded that the Board should have final authority in the management of the public service. The *Financial Administration Act* authorized the Treasury Board "to exercise all or any of the powers, other than powers of appointment, of the Governor-in-Council under the *Civil Service Act*."

7.68 The Glassco Commission of 1962 also had important implications for managing people. The government agreed to its recommendation that departments—rather than the Civil Service Commission—manage their own personnel and be accountable for their performance.

7.69 In 1967, the *Public Service Staff Relations Act* gave public service employees the right to bargain collectively and the right to strike. The Treasury Board represented the government in its bargaining relationship with government employees. Through amendments to the *Financial Administration Act*, the Treasury Board was responsible for personnel management in the public service, including determining the terms and conditions of employment and classifying positions. Under the *Public Service Employment Act*, the newly named Public Service Commission was responsible for staffing.

7.70 **Fragmented roles and responsibilities**. Although the 1979 Lambert Commission dealt mainly with financial issues, it also argued that "the management of personnel . . . is as important as, if not more important than, financial management in achieving effective overall management of government activities." Following the Commission's report, the government established the Special Committee on Personnel Management and the Merit Principle (the D'Avignon Committee). Like the Glassco and Lambert commissions, the D'Avignon Committee raised concerns about fragmented roles and responsibilities for managing people. It recommended that the Public Service Commission focus on protecting the principle of hiring and promoting staff based on merit.

7.71 In 1989, the government launched Public Service 2000 to improve service to the public through innovative approaches to management and organization. The main outcome, the *Public Service Reform Act* of 1992, brought some flexibility to the management of human resources. It also named the clerk of the Privy Council, who is also secretary to the Cabinet, a the head of the Public Service.

7.72 In the core public service, staffing is subject to the *Public Service Employment Act* and the authority of the Public Service Commission. This arrangement aims to preserve a professional, non-partisan, and representative public service, able to serve the public in the official language of their choice.

7.73 Human resource management in these core organizations is also subject to Treasury Board policies and decisions as the employer responsible for collective bargaining. These departments and agencies have had little legal authority to manage their people. They have relied on centrally prescribed systems, policies, and processes. Other government entities, known as separate employers, are subject to only some parts of these systems and have more flexibility to manage their human resources.

7.74 The need for modernizing human resource management in the federal government has been a recurrent theme in reports from the auditor general. We stated in 2001:

> The efforts of several generations of well-meaning senior officials to streamline and modernize human resource management have been stymied by the tangle of roles and responsibilities of the institutions that manage human resources and by the legislative framework that applies.

7.75 *The Public Service Modernization Act* of 2003 significantly changes the legislative and institutional framework for human resources management in the public service:

- The Treasury Board's role is significantly enhanced through a consolidation of its responsibilities as the employer.
- The Public Service Commission will refocus on the protection of merit and non-partisanship in staffing issues.
- Deputy heads will be clearly responsible in law for many aspects of human resources management.

7.76 On 12 December 2003, the government announced additional changes to human resources management:

- The Public Service Human Resources Management Agency of Canada will report to the president of the Queen's Privy Council for Canada. This new agency will strengthen human resources management and will manage implementation of the *Public Service Modernization Act*. The Agency will assume responsibility for many of the human resources management functions from the Treasury Board Secretariat, for example, organization and classification, and policy and planning.
- Responsibility for developmental training programs, such as the Management Trainee Program and the Career Assignment Program, and research to support human resources planning will be transferred from the Public Service Commission to the Agency.
- Following discussions with the public service unions, Public Works and Government Services Canada will assume responsibility for collective bargaining and other staff relations activities from the Treasury Board Secretariat.

- The Canadian Centre for Management Development (to be renamed Canada School of Public Service) which provides training, orientation, and development programs, will report to the president of the Queen's Privy Council for Canada. Training and Development Canada and Language Training Canada, now part of the Public Service Commission, will move to the Centre.

Managing information

7.77 Managing information is a more recent issue for governments than managing money and people (Exhibit 7.9). In the federal government it has three important dimensions:

- governing access to, care for, and disclosure of information held by the federal government;
- developing information systems and integrating government information to aid in decision making; and
- using information technology to improve service to Canadians.

Exhibit 7.9 Managing information: The role of the Treasury Board and the Secretariat

The Treasury Board provides the policy framework for the government's information and information technology practices. The Secretariat supports the Treasury Board's role by

- establishing policies and standards to improve management practices in departments and agencies in the areas of information and communications technology, privacy and access to information, and managing the government-wide implementation of them; and
- leading the development and implementation of certain government-wide initiatives such as Government On-Line.

Source: Treasury Board of Canada Secretariat, *Report on Plans and Priorities, 2003–04*

7.78 **Access and privacy**. The *Access to Information Act* and the *Privacy Act* became law in 1983. The *Access to Information Act* gives Canadians the right to access information in federal government records. The *Privacy Act* provides citizens with the right to access personal information held by the government and to protection of that information against unauthorized use and disclosure.

7.79 The president of the Treasury Board is the minister responsible for government-wide administration of the legislation. The Treasury Board Secretariat, as the lead agency, co-operates with the Department of Justice in amendments to the acts and with the Privy Council Office on Cabinet confidences. The Secretariat also consults with the offices of the Information and Privacy commissioners on policy matters.

7.80 **A chief information officer**. As part of its reorganization in 1993, the government established the position of chief informatics officer (now called the chief information officer) within the Treasury Board Secretariat to better align the government's information technology with its business activities.

The government estimates that it spends about $5.1 billion annually (just over 10 percent of operational expenditures) on information technology. The chief information officer focusses on the sound management of this technology across the government. For example, in 1996, the chief information officer branch led the government's efforts to deal with the Year 2000 issue.

7.81 The chief information officer is also a focal point for using information technology to improve delivery of services and reduce their costs. For example, the chief information officer led the Government On-Line initiative, a responsibility transferred to Public Works and Government Services Canada in 2003.

7.82 In 2003, the government introduced the revised Management of Government Information policy. It requires departments to use electronic systems as the preferred means of creating, using, and managing information, and to assess the effectiveness of their management of information. The revised policy includes the roles and responsibilities of all government employees for managing information.

Today's management agenda

7.83 Following the 1994–95 Program Review, the government embarked on an ambitious agenda to strengthen management across the federal public sector. In 1997, the prime minister designated the Treasury Board as the Government of Canada's management board. Three years later it released *Results for Canadians: A Management Framework for the Government of Canada.*

7.84 Since then, the government has launched several new initiatives. They cover a broad range of activities, from improving service to Canadians to strengthening values and ethics in the public service (Exhibit 7.10). The overall objective is to ensure that the key elements of good management are in place and working well together.

Exhibit 7.10 Recent management initiatives

Initiatives under *Results for Canadians: A Management Framework for the Government of Canada (2000)*

- **Citizen-Centred Service Delivery.** To improve Canadians' access to a wide range of government services and citizen satisfaction with the quality of those services.
- **Government of Canada On-Line.** To be the government most connected to its citizens and, using information and communications technologies, to provide Canadians with direct, on-line access to its information and services in both official languages.
- **Modern Comptrollership.** To strengthen government-wide policies and processes through more effective decision making, greater accountability, a mature approach to risk management, results-based control systems, and shared values and ethics.
- **Improved Reporting to Parliament.** To consult with parliamentarians on tailoring information to better meet their needs, improve channels of access and timeliness, and strengthen financial accountability by linking costs to results.
- **Program Integrity.** To identify critical risks to the existing program base for the Treasury Board and Cabinet and recommend strategies that will help departments ensure their continued achievement of results.
- **Developing an Exemplary Workplace.** Fostering public service adherence to values such as integrity, transparency, respect for diversity, and recognition of both official languages.

Other initiatives

- **Human Resources Modernization.** To update several critical components of the public service human resources management system (staffing, accountability, labour-management relations, and development).
- **Integrated Risk Management Framework.** To enable employees and organizations to better understand the nature of risk and to manage it more systematically.
- **Adoption of full accrual accounting, and study of accrual-based budgeting and appropriations.** To provide a more comprehensive accounting of the government's assets and liabilities, present a more transparent picture of its financial position, and enhance accountability, the management of liabilities, and the stewardship of assets.
- **Policy and Reporting Review Project.** To reduce the number and enhance the relevance of policy instruments and reports.
- **Revised Policy on the Management of Government Information.** To ensure that information under the control of the Government of Canada is managed effectively and efficiently throughout its life cycle.
- **Management Accountability Framework.** To reinforce sound management in the public service by providing public service managers with a comprehensive and integrated model for management and for management improvement.
- ***Values and Ethics Code for the Public Service.*** To guide and support public servants in all their professional activities, to maintain and enhance public confidence in the integrity of the public service, and to strengthen respect for, and appreciation of, the role played by the public service within Canadian democracy.

Source: Treasury Board of Canada Secretariat and related publications, *Report on Plans and Priorities, 2001–02*

Key challenges

7.85 The Treasury Board and its Secretariat play the lead role in developing and refining the government's management agenda and overseeing its government-wide implementation. In performing that role, they face a number of significant challenges. Most of these challenges cut across the four roles that we have identified—general manager, managing money, managing people, and managing information. Some are more critical for one or more of the roles.

Setting the tone from the top

7.86 Clear, visible, and active support for the management agenda among ministers, senior officials, and parliamentarians is critical for translating the agenda into concrete results. Traditionally, however, senior people paid more attention to policy than to management issues, delegating the latter to specialists.

7.87 Ten years ago, in our 1993 Report, Chapter 6, Canada's Public Service Reform and Lessons Learned from Selected Jurisdictions, we highlighted the importance of sustained leadership and support for ensuring successful reform. More recently, our April 2003 Report, Chapter 1, Integrated Risk Management, identified senior management support as key to reform's successful implementation in departments. As we stated, experience in both the public and the private sectors shows that unless senior management cultivates support and acceptance throughout the organization, reform may not take root but instead remain largely a paper exercise.

7.88 Good management is assuming greater prominence as an issue for the federal government. For example, management issues are featured explicitly in the assessments of deputy ministers and other public service executives. The corporate priorities established by the clerk of the Privy Council for 2003–04 include official languages, diversity, learning, and modern comptrollership.

7.89 *Guidance for Deputy Ministers* is another example. The Privy Council Office prepared it in 2003 to clarify how deputy ministers fulfill their role in the Government of Canada. It sets out their responsibilities, as well as their multiple accountabilities, and reflects the priority that the government attaches to management excellence. The Management Accountability Framework, released at the same time, provides all public servants with expectations concerning the various aspects of their management responsibilities.

Matching mandate and capacity of the Treasury Board and its Secretariat

7.90 The Treasury Board has a broad range of responsibilities, and its Secretariat needs knowledgeable and experienced staff for the effective review and challenge of department submissions. It also needs enough staff to manage the agenda.

7.91 While the Secretariat has grown in size, the average length of service has declined. In addition, the 2002 Public Service Employee Survey suggested that some Secretariat employees' workloads are too heavy, and they are having difficulty coping.

7.92 Our 2001 Report, Chapter 4, Voted Grants and Contributions: Government-Wide Management, raised questions about the Secretariat's capacity to meet its responsibilities. We found that, for example, the program analysts we interviewed had, on average, less than two years experience in the Secretariat. We also found a substantial loss of corporate memory as a result of Program Review and a high staff turnover.

7.93 The Secretariat's new human resources plan aims to address these issues. Still, they will likely remain a significant challenge for the Secretariat and for the government as a whole.

Strengthening department capacity

7.94 One important way to demonstrate support from the top is to ensure that departments have the resources and tools to meet their management responsibilities. We have commented in several reports that resource issues can limit departments' ability to respond fully to certain aspects of the government's management agenda.

7.95 For example, our December 2002 Report, Chapter 5, Financial Management and Control in the Government of Canada, highlighted the importance of developing a strategy to increase the number of professional accountants in senior financial positions in departments. And in our December 2001 Report, Chapter 1, Financial Information Strategy: Infrastructure Readiness, we expressed concern that the momentum may be lost as central funding is eliminated and project offices are wound down.

7.96 We have also noted that additional guidance in some areas would help departments move from policy to implementation. In our April 2002 Report, Chapter 7, Strategies to Implement Modern Comptrollership, for example, we said that clearer direction and guidance would help put into practice key aspects of modern comptrollership.

Establishing and maintaining effective working relationships with departments

7.97 The Treasury Board Secretariat, other central agencies, and departments and agencies share responsibility for development and implementation of the government's management agenda. On several occasions we have commented on the challenges posed by managing issues that span departments.

7.98 No one department has all the levers, resources, and expertise to manage all the issues adequately. They must work together toward an overall objective and adopt a common vision for success. Communication, co-operation, co-ordination, and information-sharing ensures that each organization is moving effectively in the same direction.

7.99 Given the breadth of the government's management agenda, there is a danger of confusion among ministers, parliamentarians, within the Treasury Board Secretariat itself, and across departments and agencies about where the federal government is going and about how all the pieces fit together. Considerable effort will be required by the Secretariat to respond to those two questions. Beginning with *Results for Canadians* and continuing with the *Management Accountability Framework*, the Treasury Board and its Secretariat are bringing together the various strands of the government's management agenda.

Maintaining momentum

7.100 Some of the elements of the government's management agenda are still in the early stages; others are more developed. However, any initiative that calls for significant change requires a well-developed action plan to guide its progress.

7.101 The broad picture that emerges from our historical analysis of the management agenda is one of an implementation gap—a failure to fully translate good ideas into the desired improvements in management. As a result, there is a degree of cynicism among some public servants about the current agenda's chances for success.

7.102 As noted earlier, strong leadership is needed to maintain momentum. For each reform initiative, the government needs to pay attention to the full management cycle—strategic direction, planning, implementation, monitoring, and improving—over an extended period for the management agenda to realize its potential.

Making best use of the tool kit

7.103 The government and its central agencies have several options for influencing departments and their employees in adopting its management agenda. These options include policies, resources, performance management, and reporting. The challenge is to determine what works best under what circumstances.

7.104 The Treasury Board relies on a wide range of policies to set out management expectations. A recent study by the Secretariat identified 340 policy instruments in effect. They ranged from instructions on completing financial reports to regulations related to various acts of Parliament.

7 105 In 2002, the Treasury Board of Canada Secretariat launched its Policy and Reporting Review to enable the Secretariat to

- reduce the number and enhance the relevance of policy instruments and reports;
- provide direction on important issues;
- relate policies and reporting to priorities and results;
- clarify roles, responsibilities, and accountabilities—both within the Secretariat and for departments and agencies; and
- improve the accessibility of policy instruments and target them to appropriate audiences.

Conclusion

7.106 The federal government has launched an ambitious agenda aimed at strengthening management across the public service. That agenda reflects several recurring themes in public administration: how to manage in a way that best preserves public trust, enhances economy, efficiency, and effectiveness, and ensures accountability.

7.107 In fulfilling its management role, there has been a constant tension between those who—in the name of probity, prudence, uniformity, and collective responsibility—have looked to the Treasury Board and its Secretariat to exercise central control over departments, and those who—focussing on efficiency, responsiveness, innovation, and individual responsibility—favoured empowerment and decentralized management. Today's management agenda is the most recent of a series of attempts at striking an appropriate balance.

7.108 In this chapter we identified a series of challenges that the government faces in translating this agenda into tangible improvements in management. Over the coming years, we will report on the implementation of the federal government's management agenda.

About the Study

Objectives

We conducted this study to provide Parliament with information on the key challenges that the Treasury Board and its Secretariat face in developing, refining, and implementing the federal government's management agenda. The study is a first step in the development of a longer-term audit plan for the Office, covering key elements of the federal government's management agenda, and the Treasury Board's role in them.

Scope and approach

The study examined

- the government-wide management agenda;
- the roles of Treasury Board and its Secretariat in developing and implementing the agenda;
- the challenges and risks they face; and
- how the agenda, roles, and challenges have evolved.

We began with the large body of work done by the Office on management in government. Focussing on the reports produced over the last decade, we identified key themes related to overall management within the Government of Canada and to managing money, people, and information.

We also reviewed a wide range of literature on Canadian public administration, including the reports of royal commissions, task forces, parliamentary committees, and others related to management in government. We also considered related international literature.

In addition, we reviewed a wide range of documents prepared by the Treasury Board Secretariat and drew upon the knowledge and advice of recognized experts in the field of public administration.

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